

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY, *et al.*,

Respondents.

**BRIEF FOR PETITIONERS LEAGUE OF UNITED
LATIN AMERICAN CITIZENS *ET AL.***

PATTI A. GOLDMAN
MARISA C. ORDONIA
KRISTEN L. BOYLES
Earthjustice
705 Second Avenue, Suite 203
Seattle, WA 98104
(206) 343-7340 | Phone
(206) 343-1526 | Fax
pgoldman@earthjustice.org
mordonia@earthjustice.org
kboyles@earthjustice.org
Attorneys for Petitioners

CORPORATE DISCLOSURE STATEMENT REQUIRED BY FRAP 26.1

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Petitioner's League of United Latin American Citizens, *et al.* state that they have no parent, subsidiary, or affiliate that has issued shares or debt securities to the public.

TABLE OF CONTENTS

STATEMENT OF JURISDICTION.....	1
STATEMENT OF THE ISSUES ON APPEAL	2
STATUTORY ADDENDUM	2
STATEMENT OF THE CASE.....	3
I. THE FFDCA MANDATES ELIMINATING UNSAFE PESTICIDES, PARTICULARLY THOSE THAT HARM CHILDREN, FROM OUR FOOD SUPPLY.....	4
II. EPA ENDED RESIDENTIAL USES OF CHLORPYRIFOS TO PROTECT CHILDREN FROM ACUTE POISONINGS, BUT FAILED TO PROTECT CHILDREN FROM NEURODEVELOPMENTAL HARM.	7
A. Chlorpyrifos Poisons People and Damages Children’s Brains.	7
B. EPA’s Re-Registration of Chlorpyrifos Did Not Protect Children from Learning Disabilities.	9
III. THE 2007 PETITION TO BAN CHLORPYRIFOS AND EPA’S RESPONSES.....	12
A. EPA’s Findings that Chlorpyrifos Is Unsafe and Proposal To Revoke All Tolerances.	13
1. EPA’s Rigorous Evaluations Of The Science And Multiple Peer Reviews By Its Scientific Advisory Panel Repeatedly Found That Low-Level Exposures To Chlorpyrifos Cause Neurodevelopmental Harm To Children.	13
2. EPA’s Risk Assessments And Proposed Revocation Rule Find Chlorpyrifos Unsafe.....	15
B. In 2015, EPA Proposed Revoking All Tolerances Because Chlorpyrifos Is Unsafe.	18

C. EPA’s Further Assessment of Damage to Children’s Brains Finds All Chlorpyrifos Exposures Unsafe.	19
IV. EPA’S DENIAL OF THE 2007 PETITION AND DECISION TO LEAVE CHLORPYRIFOS IN PLACE FOR FIVE OR MORE YEARS.	21
SUMMARY OF ARGUMENT	24
STANDARD OF REVIEW	26
ARGUMENT	27
I. EPA EXCEEDED ITS STATUTORY AUTHORITY AND ACTED CONTRARY TO ITS SCIENTIFIC FINDINGS IN DENYING THE 2007 PETITION.....	27
A. EPA Lacks the Statutory Authority To Maintain Chlorpyrifos Tolerances in the Absence of an Affirmative Finding that Chlorpyrifos Is Safe.....	28
B. EPA’s Findings that Chlorpyrifos Is Unsafe Compel It To Revoke the Tolerances.	30
C. A Desire to Continue Studying the Science Is Not a Legally Permissible Reason To Leave Chlorpyrifos Tolerances in Place.	34
D. The Deadline for Completing Registration Review Is Not a License To Deny the Petition and Maintain Tolerances for Unsafe Pesticides.	38
II. THIS COURT HAS JURISDICTION TO REVIEW THE SUBSTANCE OF THE PRUITT ORDER.....	41
A. This Court Should Waive Exhaustion and Hear this Case under the FFDCA.....	41
1. The Exhaustion and Judicial Review Provisions.....	42
2. The FFDCA’s Exhaustion Procedure Is, Like That Of Most Statutes, Non-Jurisdictional And Subject To Waiver.....	42

3. Exhaustion Should Be Waived.	44
B. If Exhaustion Is Required, Review of the Legality of Leaving Chlorpyrifos Tolerances in Place Is Not Obtainable under the FFDCA, Giving Rise to Review under FIFRA.	47
III. IF THIS COURT DETERMINES IT LACKS JURISDICTION, IT SHOULD ISSUE A WRIT OF MANDAMUS DIRECTING EPA TO DECIDE LULAC’S OBJECTIONS WITHIN 60 DAYS.	50
A. EPA’s Plan To Postpone Action for Five Years Violates the Rule of Reason (Factor 1).	51
B. The Statutory Scheme Calls for Speedy Action (Factor 2).	53
C. The Health Risks and Prejudice They Cause Make the Delay Unreasonable (Factors 3 and 5).	53
D. No Competing Priorities Justify EPA’s Delay (Factor 4).	58
E. EPA Appears to be Delaying for Improper Reasons (Factor 6).	58
CONCLUSION.....	59

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>In re A Community Voice</i> , 878 F.3d 779 (9th Cir. 2017)	27
<i>In re American Rivers</i> , 372 F.3d 413 (D.C. Cir. 2004).....	53
<i>Anderson v. Babbitt</i> , 230 F.3d 1158 (9th Cir. 2000)	43
<i>Arbaugh v. Y&H Corp.</i> , 546 U.S. 500 (2006).....	43
<i>Bethesda Hosp. Ass’n v. Bowen</i> , 485 U.S. 399 (1988).....	43
<i>Bowen v. Michigan Academy of Family Physicians</i> , 476 U.S. 667 (1986).....	46
<i>Chamber of Commerce of U.S. v. Reich</i> , 74 F.3d 1322 (D.C. Cir. 1996).....	46
<i>Chlorine Chemistry Council v. EPA</i> , 206 F.3d 1286 (D.C. Cir. 2000).....	33, 34
<i>Citizens for Better Forestry v. U.S. Dep’t of Agric.</i> , 341 F.3d 961 (9th Cir. 2003)	41
<i>Cutler v. Hayes</i> , 818 F.2d 879 (D.C. Cir. 1987).....	58
<i>Encino Motorcars v. Navarro</i> , 136 S. Ct. 2117 (2016).....	40
<i>Env’tl. Def. Fund, Inc. v. U.S. Dep’t of Health, Ed. & Welfare</i> , 428 F.2d 1083 (D.C. Cir. 1970).....	36

<i>Fed. Commc’n Comm’n v. Fox Television Stations</i> , 556 U.S. 502 (2009).....	39, 40
<i>Friends of the Earth v. Laidlaw Envtl. Servs.</i> , 528 U.S. 167 (2000).....	41
<i>Henderson v. Shinseki</i> , 562 U.S. 428 (2011).....	43
<i>Leedom v. Kyne</i> , 358 U.S. 184 (1958).....	46
<i>Massachusetts v. EPA</i> , 549 U.S. 497 (2007).....	29, 35
<i>McBride Cotton & Cattle Corp. v. Veneman</i> , 290 F.3d 973 (9th Cir. 2002)	45
<i>Motor Vehicles Mfrs Ass’n v. State Farm Mut. Auto. Ins. Co.</i> , 463 U.S. 29 (1983).....	26, 30, 39, 40
<i>Nader v. U.S. EPA</i> , 859 F.2d 747 (9th Cir. 1988)	44, 49
<i>Nat. Res. Def. Council v. EPA</i> , 658 F.3d 200 (2d Cir. 2011)	10
<i>Nat. Res. Def. Council v. EPA</i> , 735 F.3d 873 (9th Cir. 2013)	27
<i>Nat. Res. Def. Council v. Johnson</i> , 461 F.3d 164 (2d Cir. 2008)	49
<i>Nat’l Coalition Against Misuse of Pesticides v. Thomas</i> , 809 F.2d 875 (D.C. Cir. 1987).....	30, 31, 44
<i>Nat’l Corn Growers Assoc. v. EPA</i> , 613 F.3d 266 (D.C. Cir. 2010).....	31
<i>Nw. Coal. for Alts. to Pesticides v. U.S. EPA</i> , 544 F.3d 1043 (9th Cir. 2008)	26, 37

<i>Oestereick v. Selective Serv. System Local Bd. No. 11</i> , 393 U.S. 233 (1966).....	46
<i>Organized Village of Kake v. U.S. Dep’t of Agric.</i> , 795 F.3d 956 (9th Cir. 2015) (en banc)	40
<i>Pac. Mar. Ass’n v. Nat’l Labor Relations Bd.</i> , 827 F.3d 1203 (9th Cir. 2016)	46
<i>In re Pesticide Action Network N. Am. v. EPA</i> , 798 F.3d 809 (9th Cir. 2015)	<i>passim</i>
<i>In re Pesticide Action Network N. Am. v. EPA</i> , 863 F.3d 1131 (9th Cir. 2017)	43
<i>In re Pesticide Action Network N. Am. v. EPA</i> , 840 F.3d 1014 (9th Cir. 2016)	52
<i>In re People’s Mojahedin Organization of Iran</i> , 680 F.3d 832 (D.C. Cir. 2012).....	53
<i>In re Pesticide Action Network N. Am.</i> , 532 F. App’x 649 (9th Cir. 2013)	2
<i>Pollinator Stewardship Council v. EPA</i> , 806 F.3d 520 (9th Cir. 2015)	26
<i>Pub. Citizen Health Research Grp. v. Auchter</i> , 702 F.2d 1150 (D.C. Cir. 1983).....	52, 54
<i>Pub. Citizen Health Research Grp. v. Brock</i> , 823 F.2d 626 (D.C. Cir. 1987).....	59
<i>Pub. Citizen Health Research Grp. v. Chao</i> , 314 F.3d 143 (3d Cir. 2002)	54
<i>Pub. Citizen Health Research Grp. v. Comm’r, Food & Drug Admin.</i> , 740 F.2d 21 (D.C. Cir. 1984).....	51, 53
<i>Reed Elsevier v. Muchnick</i> , 559 U.S. 154 (2010).....	42, 43

<i>Rumbles v. Hill</i> , 182 F.3d 1064 (9th Cir. 1999)	43
<i>Sackett v. EPA</i> , 566 U.S. 120 (2012).....	48
<i>SAIF Corp./Oregon Ship v. Johnson</i> , 908 F.2d 1434 (9th Cir. 1990)	44
<i>Telecomm. Research & Action Ctr. v. FCC</i> , 750 F.2d 70 (D.C. Cir. 1984).....	<i>passim</i>
<i>U.S. Army Corps of Engineers v. Hawkes Co., Inc.</i> , 136 S.Ct. 1807 (2016).....	48
<i>Union Oil Co. of Cal. v. Fed. Power Comm’n</i> , 542 F.2d 1036 (9th Cir.1976)	27
<i>United Farm Workers v. Adm’r, Env’tl. Prot. Agency</i> , 592 F.3d 1080 (9th Cir. 2010)	47
<i>Universal Camera Corp. v. Nat’l Labor Relations Bd.</i> , 340 U.S. 474 (1951).....	27
<i>Weinberger v. Salfi</i> , 422 U.S. 749 (1975).....	42, 44
<i>Whitman v. American Trucking Assoc.</i> , 531 U.S. 457 (2001).....	30

Statutes

5 U.S.C. §704	43
5 U.S.C. §706(2)	26
7 U.S.C. §136a(c)(5).....	47
7 U.S.C. §136a(g)(1)(A)(i)	7
7 U.S.C. §136a(g)(1)(A)(iii)(I)	7, 37
7 U.S.C. §136a(g)(1)(C)	38

7 U.S.C. §136d(b)	48
7 U.S.C. §136d(bb)	48
7 U.S.C. §136n(b)	1, 26, 47
7 U.S.C. §136w(d)	13
21 U.S.C. §346a(b)(2)(A)(i)	<i>passim</i>
21 U.S.C. §346a(b)(2)(C)	6, 34, 53
21 U.S.C. §346a(b)(2)(D)	6
21 U.S.C. §346a(d)(5)	44
21 U.S.C. §346a(g)(6)	42
21 U.S.C. §346a(h)(1)	1, 42
21 U.S.C. §346a(h)(5)	1, 49
Food Quality Protection Act, Pub. L. No. 104–170, August 3, 1996, 110 Stat 1489	49

Regulatory Materials

40 C.F.R. §180.342	7, 11
80 Fed. Reg. 69,080 (Nov. 6, 2015)	18
81 Fed. Reg. 81,049 (Nov. 17, 2016)	21
82 Fed. Reg. 16,581 (Apr. 5, 2017)	<i>passim</i>

STATEMENT OF JURISDICTION

This case seeks review of the order issued by Environmental Protection Agency (“EPA”) Administrator Scott Pruitt denying a 2007 Petition to cancel all tolerances for the pesticide chlorpyrifos. 82 Fed. Reg. 16,581, 16,583 (Apr. 5, 2017) (“Pruitt Order”). Within 60 days of issuance of that order, Petitioners League of United Latin American Citizens *et al.* (“LULAC”) timely filed administrative objections with EPA and this petition for review, challenging the substance of the Pruitt Order. This Court has jurisdiction under the Federal Food, Drug, and Cosmetic Act (“FFDCA”), 21 U.S.C. § 346a(h)(1), and this Court should waive statutory exhaustion procedures as they would be futile and perpetuate the violations of the FFDCA. If this Court holds that judicial review pursuant to 21 U.S.C. § 346a(h)(1) must wait until the EPA Administrator rules on the objections, this Court has jurisdiction under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. § 136n(b), because, in that event, meaningful and timely judicial review would not be obtainable under the FFDCA. *See* 21 U.S.C. 346a(h)(5) (where judicial review of an issue is obtainable under the FFDCA, it is not reviewable under any other provision of law).

Pursuant to the All Writs Act, 28 U.S.C. § 1651, this Court has authority to issue a writ of mandamus. It has jurisdiction to issue such a writ to stop EPA’s delay in ruling on the objections because challenges to EPA’s action on the

objections lie in this Court. *See In re Pesticide Action Network N. Am.*

(“*PANNA*”), 532 F. App’x 649, 650 (9th Cir. 2013).

STATEMENT OF THE ISSUES ON APPEAL

1. Whether Administrator Pruitt exceeded his authority and acted contrary to the FFDCA and EPA’s scientific findings that chlorpyrifos is unsafe, when he denied the 2007 Petition and left chlorpyrifos tolerances in place for five or more years?
2. Whether this Court can and should waive exhaustion of administrative remedies because it would be futile and would perpetuate the violations of the FFDCA to wait for EPA to rule on the objections?
3. If the Court lacks the authority to waive exhaustion under the FFDCA, whether it has jurisdiction under FIFRA because judicial review would otherwise be unobtainable?
4. In the alternative, whether EPA is unreasonably delaying ruling on the objections when it plans to put off deciding them until it takes regulatory action in four or five years?

STATUTORY ADDENDUM

An addendum containing relevant statutory provisions is bound to this brief.

STATEMENT OF THE CASE

This case seeks to put an end to EPA’s failure to protect people—particularly children—from a pesticide that causes large numbers of acute poisonings every year and damages children’s developing brains. It challenges the Pruitt Order, which denied a 2007 Petition to ban this pesticide and left chlorpyrifos tolerances in place for five or more years. Alternatively, this case challenges the Administrator’s plan to delay ruling on objections to his order for the same five-year period. To put these delays in context, this brief begins by describing the FFDCA’s mandates to protect children from unsafe pesticides; EPA’s longstanding failure to comply with this standard despite extensive scientific evidence that early life exposures to chlorpyrifos damage children’s brains; the agency’s findings, upon evaluating the this evidence, that chlorpyrifos causes neurodevelopmental harm and is unsafe; its proposal to ban chlorpyrifos because it is unsafe; and the abrupt reversal and denial of the 2007 Petition by Administrator Pruitt, not because he found chlorpyrifos safe, but because he prefers to postpone regulatory action.

This Court is no stranger to this quest to protect children from neurodevelopmental harm. In 2015, this Court issued a writ of mandamus upon finding EPA’s delay in acting on the 2007 Petition “egregious” and court-ordered deadlines “necessary to end this cycle of incomplete responses, missed deadlines,

and unreasonable delay.” *In re PANNA v. EPA*, 798 F.3d 809, 811, 813 (9th Cir. 2015). This case challenges the substance of the Pruitt Order, which denied the Petition to revoke chlorpyrifos tolerances, or, in the alternative, the unreasonable delay inherent in the Administrator’s plans to slow walk resolving the objections. Now as before “EPA has offered no acceptable justification for the considerable human interests prejudiced by the delay.” *Id.* at 814.

I. THE FFDCA MANDATES ELIMINATING UNSAFE PESTICIDES, PARTICULARLY THOSE THAT HARM CHILDREN, FROM OUR FOOD SUPPLY.

Under the FFDCA, EPA must establish the maximum residue of a pesticide allowed on food, called a “tolerance,” in order for a pesticide to be permitted on food that is imported or sold in interstate commerce. 21 U.S.C. § 346a(b) & (c). EPA must set tolerances at levels that ensure the food is safe. *Id.* § 346a(b)(2)(A)(i).

In 1996, Congress unanimously passed the Food Quality Protection Act (“FQPA”) to respond to a seminal 1993 National Academy of Sciences (“NAS”) report – Pesticides in the Diets of Infants and Children – recommending that EPA stop regulating pesticides based solely on their effects on adult men. The NAS report documented the ways that children are not little adults because of their unique exposures from the foods they eat, their play, their metabolism, and windows of developmental vulnerability. For example, six-month old children

drink seven times more per body weight than adults, inhale twice as much air, and put their hands in their mouths far more often than adults. In addition, during sensitive life stages (in utero, infancy, and adolescence), toxic chemicals can damage the developing brain at lower exposures than those that affect adults. AR 2180; ER 1880-04 (Declaration of Dr. Philip J. Landrigan (Sept. 7, 2016)).¹

The FQPA strengthened the food safety standard, added provisions to protect children, and established timelines for EPA to ensure old pesticides are compliant. First, under the amended FFDCA, the EPA Administrator “may establish or leave in effect a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.” 21 U.S.C. § 346a(b)(2)(A)(i).

Second, safe “means the Administrator has determined there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” *Id.* § 346a(b)(2)(A)(ii). EPA

¹ “AR” refers to the certified index to the administrative record, ECF 32-2 and 36-2; “ER” to the excerpts of record filed concurrently with this brief. Dr. Landrigan chaired the NAS Committee that conducted the five-year study and published the 1993 NAS report. His declaration was submitted with LULAC’s second set of comments on the proposed revocation rule. AR 1512.

must protect against aggregate exposures from all sources combined, whether from eating foods, drinking water, breathing air near the fields, or playing and rolling around on treated fields or carpets. *Id.* § 346a(b)(2)(A)(ii), (C)(i)(I), (D)(vi).

Third, EPA must make specific safety determinations for infants and children. *Id.* § 346a(b)(2)(C)(ii)(I) & (II). It must consider available information concerning “the special susceptibility of infants and children,” including “neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals.” *Id.* § 346a(b)(2)(C)(i)(II). EPA must also base its tolerance decisions on available information about “food consumption patterns unique to infants and children.” *Id.* § 346a(b)(2)(C)(i)(I) & (III).

Fourth, EPA must account for children’s sensitivities, scientific uncertainty, or gaps in available data. The statute requires that “an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre -and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.” *Id.* § 346a(b)(2)(C). EPA can depart from this requirement and use a different margin of safety “only if, on the basis of reliable data, such margin will be safe for infants and children.” *Id.*

Finally, Congress gave EPA ten years, until August 2006, to bring old pesticides, like chlorpyrifos, into compliance with the food safety standards. *Id.* §

346a(q)(1). EPA must also continue to review pesticides every fifteen years, in a process called registration review, to ensure they meet FFDCA and other legal standards based on evolving scientific information. 7 U.S.C. § 136a(g)(1)(A)(i), (iii)(II).

II. EPA ENDED RESIDENTIAL USES OF CHLORPYRIFOS TO PROTECT CHILDREN FROM ACUTE POISONINGS, BUT FAILED TO PROTECT CHILDREN FROM NEURODEVELOPMENTAL HARM.

A. Chlorpyrifos Poisons People and Damages Children's Brains.

Chlorpyrifos is a widely used organophosphate pesticide first registered by EPA in 1965. It is used on an extensive variety of food and feed crops, including on foods eaten by children like apples, peaches, nectarines, pears, grapes, cherries, oranges, strawberries, and bananas. 40 C.F.R. §180.342 (chlorpyrifos tolerances); AR 1408, attachment 1 (EPA 2014 dietary risk assessment). People are exposed to chlorpyrifos when it forms residues on foods, concentrates in drinking water, and drifts through the air.

Organophosphates, developed as nerve agents in World War II, have deleterious effects on people through inhalation, ingestion, eye contact, and absorption through the skin. Organophosphates disrupt the proper functioning of the nervous system by suppressing an enzyme called acetylcholinesterase. When cholinesterase activity is inhibited, nerves are over-stimulated, causing people to experience symptoms such as headaches, nausea, dizziness, difficulty breathing,

vomiting, diarrhea, muscle spasms, seizures, skin rashes, and at very high exposures, convulsions, respiratory paralysis, comas, and even death. ER 1138. Chlorpyrifos is associated with a significant number of acute pesticide poisoning incidents every year. *See, e.g.*, ER 1521-28 (Washington State poisoning incidents); ER 1483-1511 (California poisoning incidents).

A growing body of published scientific research from both animal and epidemiology studies links exposure to chlorpyrifos with neurodevelopmental harm to children. Children's brains are particularly vulnerable to damage from low-dose exposures because the placenta is not a barrier to passage of many toxic chemicals, including chlorpyrifos, from the mother to the fetus. ER 1804-07. Experimental studies on laboratory animals reveal cognitive, motor control, and social behavior deficits from chlorpyrifos exposures. ER 309-403 (EPA evaluation of experimental toxicology data).

Three human population studies funded by the U.S. Centers for Children's Environmental Health produced more than a dozen peer-reviewed published articles correlating prenatal organophosphate exposure with learning disabilities in children. A long-term study conducted by the Columbia Center on Children's Environmental Health correlated chlorpyrifos levels in African American and Dominican pregnant women in New York City (measured in umbilical cord blood at the time of delivery) with adverse neurodevelopmental effects in their children.

The study began before and continued after the residential chlorpyrifos ban. The children born after the ban had dramatically lower chlorpyrifos levels. At age three, the highly exposed children had statistically significant delays in motor and mental development. At age seven, they experienced attention disorders, reduced IQ, and loss of working memory. At age eleven, the children had more arm tremors and reduced fine motor control that affected the children's ability to draw shapes. ER 404-565 (EPA detailed synthesis of three cohort studies); ER 1258-61 (2016 update). Subsequent testing using magnetic resonance imaging ("MRI") revealed physical brain abnormalities in an area of the brains of highly exposed children linked to learning, cognition, and social behaviors. AR 2196.

The Columbia study's findings are consistent with those of two other mother-child pair studies that correlated prenatal exposures to organophosphates with learning disabilities. A University of California-Berkeley study followed a cohort of children born to farmworkers in Salinas Valley, California, and found reduced IQ, verbal comprehension, perceptual reasoning, and working memory. A study conducted at Mount Sinai School of Medicine observed a New York City Hispanic population and found similar learning disabilities in the children. ER 404-565 (EPA synthesis), 1084-88 (EPA literature review).

B. EPA's Re-Registration of Chlorpyrifos Did Not Protect Children from Learning Disabilities.

The FQPA directs EPA to determine safety based on an assessment of the

pesticide's risk generally and specifically for infants and children. 21 U.S.C. § 346a(b)(2)(C) (EPA "shall assess the risk" of the pesticide). EPA's risk assessment process integrates information on toxicity and exposure. First, EPA determines the most sensitive critical effect and an exposure level that has no adverse effect, unless the pesticide causes harm at any exposure level. ER 1136. Second, EPA applies traditional safety factors to account for uncertainties in extrapolating from animal studies to people and for variations among human populations, and under the FQPA, EPA adds an additional margin of safety to account for potential pre- and post-natal toxicity and completeness of the toxicology and exposure data sets. Each safety factor is typically tenfold. ER 1137. When EPA applies all three safety factors, exposures must be 1000 times less than the no-effect level in order to be safe. *See Nat. Res. Def. Council v. EPA*, 658 F.3d 200, 201, 207-09 (2d Cir. 2011) (describing risk assessment process and congressional intent to add the FQPA safety factor to the traditional safety factors). The Second Circuit described use of a three-fold safety factor as "similar to an engineer who estimates that a bridge must hold X weight, and then designs the bridge in a way that she believes will hold 3X weight, to create a margin of safety based on prior engineering practice." *Id.* at 208. Third, EPA assesses whether predicted exposures, when aggregated, are less than the safe level. ER 1137-39.²

² EPA's process is rich in the use of acronyms. NOAEL refers to the no observed

If so, the scientific record supports finding reasonable certainty of no harm and setting the pesticide tolerance at this level.

EPA's initial risk assessments for chlorpyrifos assumed that 10% cholinesterase inhibition in red blood cells was the most sensitive endpoint. In 2000, EPA determined that children crawling on treated carpets and hugging pets after flea treatments faced unsafe chlorpyrifos exposures and ended all homeowner uses of chlorpyrifos. ER 28. When EPA issued its interim chlorpyrifos re-registration in 2001, it allowed uses to continue on many dozens of food crops. 40 C.F.R. § 180.342 (chlorpyrifos tolerances).

Public comments on EPA's 2001 interim re-registration determination for chlorpyrifos urged EPA to address the scientific evidence showing that neurodevelopmental impacts to children at doses lower than those that cause 10% cholinesterase inhibition. ER 87-120; AR 277, Exh. 2. In 2006, after releasing its cumulative organophosphate risk assessment, EPA finalized its re-registration of chlorpyrifos without protecting children from neurodevelopmental harm and without addressing the public comments.³

adverse effect level, LOAEL to a low observed adverse effect level, point of departure is the low or no effect level for the most sensitive endpoint, tenfold safety factors are abbreviated to 10X, and reference dose or RfD is derived by applying safety factors to the point of departure and is what EPA deems to be safe. *See, e.g.*, ER 1136; ER 1270.

³EPA, Finalization of Interim Re-Registration Eligibility Determination for Chlorpyrifos (July 31, 2006), available at

III. THE 2007 PETITION TO BAN CHLORPYRIFOS AND EPA'S RESPONSES.

In September 2007, PANNA and Natural Resources Defense Council (“NRDC”) petitioned EPA to ban chlorpyrifos based on the mounting evidence of risks from chlorpyrifos that were left unaddressed in EPA’s 2001 and 2006 regulatory decisions. The 2007 Petition compiled evidence, including peer-reviewed scientific studies, showing that children and infants exposed prenatally to low doses of chlorpyrifos suffer from long-lasting learning disabilities. ER 6-9, 11-13, 22-13.⁴

Because the organophosphates pose complex scientific issues that EPA had not previously addressed, EPA prioritized registration review of the organophosphates. ER 1135. EPA moved chlorpyrifos to the head of the line in order to respond to the 2007 Petition and planned to propose regulatory actions in 2014 and finalize them in 2015. ER 28; AR 1437 (Final Work Plan); Decl. of Jack Housenger, Director of the Health Effects Division, EPA’s Office of Pesticide Programs ¶ 13, *In re PANNA*, No. 12-71125 (9th Cir. July 23, 2012) (Dkt. 9-2).

https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/ired_PC-059101_28-Sep-01.pdf.

⁴ The 2007 Petition also sought protections for children and bystanders from chlorpyrifos that moves from fields where it is sprayed to schools, day cares, and homes and presented air monitoring data documenting chlorpyrifos concentrations above EPA’s levels of concern near fields and in schoolyards. ER 17-21.

A. EPA's Findings that Chlorpyrifos Is Unsafe and Proposal To Revoke All Tolerances.

EPA engaged in what it repeatedly described as “a stepwise, objective and transparent approach to evaluate, interpret, and characterize the strengths and uncertainties associated with all the lines of scientific information related to the potential for adverse neurodevelopmental effects in infants and children as a result of prenatal exposure to chlorpyrifos.” ER 202.

1. *EPA's rigorous evaluations of the science and multiple peer reviews by its Scientific Advisory Panel repeatedly found that low-level exposures to chlorpyrifos cause neurodevelopmental harm to children.*

In 2008, EPA initiated a rigorous, iterative review of the scientific evidence with several rounds of review by the Scientific Advisory Panel (“SAP”), established to provide peer review of science used by EPA in making pesticide determinations. 7 U.S.C. § 136w(d). With increasing confidence over time, EPA and the SAP repeatedly found that “chlorpyrifos is likely associated with adverse neurodevelopmental outcomes” from low-level exposures. ER 817 (SAP Minutes on EPA's Evaluation of Toxicity Profile of Chlorpyrifos (Sept. 2008)); *accord* ER 787, 811. EPA and the SAP first made this finding in 2008, when both called the Columbia study sound and robust, ER 786, 806, and Panel members expressed concerns that low-level exposures to chlorpyrifos, like lead and mercury, produce significant adverse effects when they previously were thought to be harmful only

at high levels. ER 817.

In 2012, the SAP reviewed EPA's comprehensive analysis of experimental animal studies and the three mother-child pair studies from Columbia, Mt. Sinai, and California. The SAP concluded that, in addition to laboratory animal studies showing significant, long-term adverse effects on neurobehavioral development, epidemiology "studies show some consistent associations relating exposure measures to abnormal reflexes in the newborn, pervasive development disorder at 24 or 36 months, mental development at 7-9 years, and attention and behavior problems at 3 and 5 years of age." ER 971 (SAP Minutes on EPA's Evaluation of Chlorpyrifos Health Effects (Apr. 2012)); ER 853-955 (EPA's 2012 analysis).

The Panel found that "multiple lines of evidence suggest chlorpyrifos can affect neurodevelopment at levels lower than those associated with [cholinesterase] inhibition." ER 973; *accord* ER 979 (cholinesterase inhibition could not have been responsible for the cognitive defects or developmental delays). The Panel advised EPA to explore ways to use the Columbia study to identify doses associated with the damage to the developing brain. ER 973-74.

EPA reviewed new studies as they were published, including one correlating chlorpyrifos with autism, ER 1784, and new information that reduced uncertainties to the point that EPA found any errors were more likely to underestimate, rather than overestimate, the association between chlorpyrifos exposures and harm to

children's brains. ER 923, 927, 951-52. EPA expanded its review to include the scientific literature on all organophosphate pesticides and found that low-level exposures to other organophosphates also damage children's brains. ER 1031-1131 (Literature Review of Neurodevelopmental Effects (Sept. 15, 2015)). In its most recent proceedings in 2016, the SAP again found there is evidence from epidemiology and toxicology studies of "adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% red blood cell [cholinesterase] inhibition (*i.e.*, toxicity at lower doses)." ER 1191, 1195, 1198, 1225-26 (2016 SAP Minutes on Analysis of Chlorpyrifos Biomonitoring Data (July 20, 2016)).

2. *EPA's risk assessments and proposed revocation rule find chlorpyrifos unsafe.*

In 2011, EPA released a preliminary human health risk assessment for chlorpyrifos that focused on cholinesterase inhibition, not neurodevelopmental harm. This risk assessment documented risks of concern from drinking water and drift exposures. AR 1367; ER 1135.

In December 2014, EPA released its Revised Human Health Risk Assessment ("2014 Assessment"), finding, based on laboratory and human studies, that chlorpyrifos causes learning disabilities and other damage to children's brains at low-level exposures. ER 184, 209 ("a pattern of neurodevelopmental adverse outcomes emerges"); *id.*, ER 208, 210 (laboratory animal studies indicated "that

gestational and/or postnatal exposure may cause persistent behavioral effects into adulthood,” including at doses in a recent study that would not induce cholinesterase inhibition). While EPA could not identify the mechanism by which chlorpyrifos causes brain damage from prenatal exposures, its policies do not allow EPA to ignore causality based on an inability to identify the mode of action. ER 231.

Drawing from its extensive review and the 2008 and 2012 SAP reports, EPA found that the three mother-child pair studies “are strong studies which support a conclusion that chlorpyrifos likely played a role in” causing the neurodevelopmental harm. ER 216. As to the Columbia study, EPA cited the findings of “a 2-4 fold increase in reduced mental and also psychomotor development in infants exposed to chlorpyrifos *in utero*,” “statistically significant evidence of differences in the proportion of pervasive developmental disorder diagnoses between children in the high and low exposures groups” at three years of age, and “reduced measures of intelligence” at seven years of age. ER 221. The similar findings in the California and Mt. Sinai studies of pervasive development disorders and reduced IQ from organophosphate exposures, reinforced the findings that “chlorpyrifos results in adverse neurodevelopmental outcomes in humans.” ER 215, 221-23, 225, 232.

EPA, like the 2012 SAP, concluded that the exposures in the Columbia study were lower than those that cause cholinesterase inhibition. ER 224, 228; *see* ER 230 (“it is unlikely that [cholinesterase] would have been inhibited by any meaningful or measureable amount, if at all” in the studies). EPA’s risk assessment therefore was not based on the most sensitive endpoint and did not protect against damage to children’s brains because it used 10% cholinesterase inhibition to assess safety.⁵ Because the mode of action and specific exposure level at which chlorpyrifos damages children’s brains is uncertain, EPA retained the FQPA tenfold safety factor for infants, children, youth, and women of child-bearing years. ER 232.

Even without protecting children from learning disabilities, EPA’s models showed that chlorpyrifos uses will result in exposures that exceed EPA’s drinking water levels of concern, particularly in agricultural areas, and monitoring data confirmed the results. ER 194, 271-73, 276-78.⁶

⁵ Numerous scientific experts criticized EPA’s risk assessment for using exposures associated with cholinesterase inhibition and not an exposure limit that would guard against damage to the developing brain. *See, e.g.*, ER 1514 (Professor Elaine Faustman, University of Washington (Apr. 30, 2015); ER 1335 (Comment submitted by Professors Robin M. Whyatt, Columbia University, Dale Hattis, Clark University and Theodore Slotkin, Duke University (Apr. 30, 2015); ER 1787 (comment from 49 scientists and health-care professionals); *see also* ER 1391 (Farmworker, Health, and Conservation Group Comments at 28-32 (Apr. 30, 2015))).

⁶ The 2014 Assessment also found risks of concern to many workers who mix and apply chlorpyrifos or re-enter fields to perform tasks like picking and thinning after

B. In 2015, EPA Proposed Revoking All Tolerances Because Chlorpyrifos Is Unsafe.

In October 2015, reiterating the findings in the 2014 risk assessment, EPA proposed to revoke all chlorpyrifos tolerances because of drinking water contamination, effective 180 days after a final rule is published. ER 1133, 1135-36, 1159 (80 Fed. Reg. 69,080 (Nov. 6, 2015)). EPA “is unable to conclude that the risk from aggregate exposure from the use of chlorpyrifos meets the safety standard,” with infants most at risk. ER 1134; *see also id.* (“EPA cannot, at this time, determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all non-occupational exposures for which there is reliable information, are safe.”). “Because EPA is unable to determine at this time that aggregate exposures to chlorpyrifos are safe, EPA is proposing to revoke these tolerances.” ER 1134.

The proposed rule acknowledged that the 2014 risk assessment fails to protect children from learning disabilities that occur at exposures below EPA’s cholinesterase inhibition endpoint. ER 1140, 1143. EPA planned to continue reviewing the evidence of long-lasting damage to children’s brains from low-level exposures in order to develop a more protective endpoint for its regulatory determination. ER 1148.

chlorpyrifos has been sprayed on the crop. ER 195-96, 285-86, 288-90.

Based on its drinking water assessment, EPA found that drinking water exposures present risks of concern, particularly for infants and children in agricultural watersheds. ER 1136, 1150, 1156. EPA solicited mitigation proposals that might make some chlorpyrifos uses safe. *Id.* at 69,080, 69,085, 69,104, 69,106. Public comments continued to urge EPA to develop an endpoint or use additional safety measures to protect children from this harm. *See, e.g.*, ER 1529.

C. EPA's Further Assessment of Damage to Children's Brains Finds All Chlorpyrifos Exposures Unsafe.

After issuing the proposed rule, EPA sought to identify an exposure level that would protect against damage to children's brains from low-level exposures. In 2016, EPA used measurements of chlorpyrifos in cord blood from the Columbia study to derive a more protective endpoint. The SAP reviewed and did not support EPA's use of cord blood because of insufficient data on its relationship to the exposures at the time of the chlorpyrifos applications, although it continued to find that regulating to prevent 10% cholinesterase inhibition is "not adequately protective of human health." ER 1195; *accord* ER 1191, 1198, 1225.

In November 2016, EPA updated its risk assessment and strengthened its findings of harm to children. ER 1249, 1253-55, 1258, 1261 (2016 Update at (Nov. 3, 2016)). EPA reiterated its findings that damage to children's brains occurred below exposures that result in 10% cholinesterase inhibition. 2016 Update at 1262; ER 1290, 1291 (agreeing with the SAP that existing endpoint

based on 10% cholinesterase inhibition is “not sufficiently health protective”).

Following the 2012 SAP’s recommendation, EPA established an exposure level associated with neurodevelopmental harm by using data from the Columbia study and a model developed by Dow Agrosiences. EPA estimated exposures based on the chlorpyrifos application method used in the public housing at the time of exposure in the Columbia study and identified time-weighted average blood concentrations for the pregnant women in the Columbia study. ER 1252-53, 1262-65 (2016 Update).⁷ Using this endpoint, EPA found that chlorpyrifos presents unacceptable safety risks through exposures from food, drinking water, spray drift, volatilization, and worker activities. Food-only exposures for chlorpyrifos were found to be unsafe for all populations, with young children facing the highest risks of concern. ER 1254, 1271-72. While adult exposures are an alarming 62 times higher than the safe level, children ages 1-2 face risks more than 140 times higher than safe levels. ER 1254, 1271. EPA continued to find that “the majority of estimated drinking water exposures from currently registered uses, including water exposures from non-food uses, continue to exceed safe levels even taking into

⁷ EPA used a model developed by Dow Agrosiences (called a physiologically based pharmacokinetic model) to estimate doses in people associated with particular specified effects, like cholinesterase inhibition or neurodevelopmental harm. In applying that model in the update, EPA retained the FQPA tenfold safety factor based on its policy of accounting for uncertainty when using an exposure that caused some rather than no adverse effects. ER 1252, 1270.

account more refined drinking water exposures.” ER 1291. Regarding spray drift, EPA found unsafe chlorpyrifos levels from the field’s edge to distances of more than 300 feet from where the pesticide is sprayed. ER 1254, 1279. EPA also found unsafe levels of chlorpyrifos recorded in air monitoring in agricultural communities in California and Washington. ER 1254-55, 1279-82. In addition, EPA found unacceptable risks to all farmworkers who mix and apply chlorpyrifos or re-enter the fields within 18 days of chlorpyrifos spraying. ER 1255, 1284-86.

After releasing the 2016 Update, EPA reopened the comment period for its proposal to revoke chlorpyrifos tolerances and emphasized that its updated risk analysis “indicates that expected residues of chlorpyrifos on most individual food crops exceed the ‘reasonable certainty of no harm’ safety standard” and that most drinking water exposures “continue to exceed safe levels” ER 1249, 1291 (81 Fed. Reg. 81,049, 81,050 (Nov. 17, 2016)). EPA reiterated that “it can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe” and its updated analysis “continues to indicate that the risk from the potential aggregate exposure does not meet the FFDCA safety standard.” *Id.*

IV. EPA’S DENIAL OF THE 2007 PETITION AND DECISION TO LEAVE CHLORPYRIFOS IN PLACE FOR FIVE OR MORE YEARS.

EPA had a March 31, 2017 deadline from this Court to make a final decision on the 2007 Petition. As of early March 2017, EPA was on track to finalize the proposed revocation based on its findings that chlorpyrifos is unsafe. After Scott

Pruitt became EPA Administrator and his political assistants met with the Acting Administrator overseeing EPA's chemicals and pesticides programs, EPA's direction shifted 180 degrees.⁸ At a meeting on March 3, 2017, the Administrator's chief of staff indicated he did not want EPA forced into a box by the 2007 Petition and directed the Acting Assistant Administrator to provide a briefing paper with other options. Exh. C at 1-2. He later told colleagues that EPA staff "are trying to strong arm us. I scared them Friday", "but they know where this is headed." Exh. B at 17. One option would have entailed a full or partial phase-out over time, but Dow resisted agreeing to a phase-out after the election. Exh. C at 1-2. The Chief of Staff chose another option described as "legalistic arg[uments]" pertaining to a new administration's ability to have different priorities. Exh. C at 2.⁹ A draft denial was circulating by March 16, 2017,

⁸ This paragraph is drawn from EPA records that have been made publicly available and are attached as Exhibits A-F to the Declaration of Marisa Ordonia (Jan. 19, 2018). They are relevant to LULAC's futility argument and request for mandamus relief, neither of which is reviewed on the basis of an administrative record. In addition, LULAC is filing a motion to complete the record by adding these documents to it.

⁹ During this same period of time, the Administrator and members of the transition team met with the members of the American Farm Bureau Federation, who made a plea for "a reasonable approach" involving the agricultural sector in the chlorpyrifos decision. Exh. B at 1-5 (Summary of March 1, 2017 Meeting). Mr. Pruitt told the participants that "this is a new day, a new future, for a common sense approach to environmental protection." *Id.* The following week, Mr. Pruitt met with the CEO of Dow Agrosciences. Exh. A (Pruitt Calendar for March 9, 2017).

finalized and signed by the Administrator on March 29, 2017, and released with a press release announcing that EPA is “reversing the previous Administration’s steps to ban one of the most widely used pesticides” and “the need to provide regulatory certainty to American farms that rely on chlorpyrifos.” Exh. B at 22-35, 43.

The Pruitt Order denied the 2007 Petition “in full” and maintained chlorpyrifos tolerances. ER 25, 27 (82 Fed. Reg. 16,581 (Apr. 5, 2017)). It cut and pasted a series of prior interim responses to drift, volatilization, and other issues raised in the 2007 Petition.¹⁰ As to the one issue EPA had not previously resolved — neurodevelopmental harm from chlorpyrifos — the Pruitt Order denied the Petition and left chlorpyrifos tolerances in place because of the significance of the decision given the widespread use of chlorpyrifos and a preference to engage in further study before finalizing the October 2015 proposed revocation rule or taking an alternative regulatory path. ER 34. The Pruitt Order neither revoked the proposed rule, nor revisited EPA’s findings that chlorpyrifos is unsafe. It put off

¹⁰ Much of the Pruitt Order defends EPA’s 2006 re-registration determination, but EPA cannot rely on its 2006 safety finding in light of EPA’s additional decade of analysis and subsequent findings that chlorpyrifos is unsafe. *See* 21 U.S.C. § 346a(d)(4) (EPA must assess available information); *id.* § 346a(b)(2)(C)-(D) (EPA must consider available information concerning such factors as toxicity, population sensitivities, and children’s exposures). As this Court noted, EPA “has backtracked significantly from” its 2006 pronouncement of safety when it found chlorpyrifos unsafe in its 2014 risk assessment and determined its tolerances needed to be revoked. *In re PANNA*, 798 F.3d at 814.

chlorpyrifos tolerance decisions until as far off as October 1, 2022, when it must complete the review of all the older pesticides under the FIFRA timelines. ER 34.

Within 60 days, LULAC filed objections that initiated an administrative appeal and this lawsuit. ER 121-64. Several states also filed administrative objections. ER 165-83. The objections raise purely legal issues and do not seek an evidentiary hearing. EPA has yet to acknowledge receipt of the administrative objections. In a December 2017 response to a request from three U.S. Senators that it rule on the objections expeditiously, EPA indicated that it plans to prepare another risk assessment, seek public comments, propose a new regulatory decision, seek another round of comments, and then make a final regulatory decision for chlorpyrifos. It has offered no timeline for a final decision, but the timelines for the interim stages suggest a final decision in 2021-2022. Exh. D-F.

SUMMARY OF ARGUMENT

In the face of a series of unbroken EPA findings that chlorpyrifos is unsafe, Administrator Pruitt could not and did not purport to find chlorpyrifos safe. Nonetheless, he issued an order denying the Petition to ban chlorpyrifos and leaving chlorpyrifos tolerances in place for five or more years. In doing so, Administrator Pruitt exceeded his statutory authority under the FFDCA, which allows him to leave a tolerance in effect “only if [he] determines that the tolerance

is safe,” and requires that he revoke tolerances determined to be unsafe. 21 U.S.C. § 346a(b)(2)(A)(i).

EPA’s findings that chlorpyrifos is unsafe compel revocation of all chlorpyrifos tolerances. EPA found chlorpyrifos unsafe due to drinking water contamination in 2014, leading to the 2015 proposal to revoke all tolerances. When EPA set a regulatory endpoint that would prevent damage to children’s developing brains, it found unsafe exposures in every way that people come into contact with chlorpyrifos – whether in food, in drinking water, or in the air—with infants most at risk. The record seals the fate of chlorpyrifos. It is arbitrary and capricious for EPA to act contrary to its own scientific findings and to deny the Petition for reasons other than safety, which is the only determinant under the FFDCA. The fact that there is some scientific uncertainty in pinpointing the precise exposure that causes brain damage to children is no defense. Nor is the 2022 deadline for completing registration review of all older pesticides a license to retain tolerances for this unsafe pesticide. The Court should reverse and remand to EPA with directions to revoke all chlorpyrifos tolerances.

Ordinarily, judicial review of a tolerance decision occurs after EPA rules on administrative objections, but exhaustion is not a jurisdictional prerequisite. This Court should waive exhaustion because it would be futile and perpetuate the legal violations in light of EPA’s plans to engage in years of study before taking

regulatory action and ruling on the objections in four to five years. If exhaustion is required, review of EPA's illegal conduct is not obtainable under FFDCA and should proceed under FIFRA. Alternatively, if the Court believes a ruling on the objections is jurisdictionally required, it should issue a writ of mandamus directing EPA to rule on objections within 60 days.

STANDARD OF REVIEW

The Pruitt Order's compliance with the FFDCA is reviewed under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706. *Nw. Coal. for Alts. to Pesticides v. U.S. EPA*, 544 F.3d 1043, 1047 (9th Cir. 2008). Under the APA, the court shall hold unlawful and set aside an agency action found to be "in excess of statutory jurisdiction, authority, or limitation . . ." or "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A), (C). An agency decision is arbitrary and capricious if "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicles Mfrs Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Under FIFRA, a court shall uphold EPA’s determination “if it is supported by substantial evidence when considered on the record as a whole.” 7 U.S.C. § 136n(b); *see Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 528 (9th Cir. 2015). “Substantial evidence means more than a mere scintilla but less than a preponderance; it is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Nat. Res. Def. Council v. EPA*, 735 F.3d 873, 877 (9th Cir. 2013). The substantial evidence standard affords an agency less deference than the arbitrary and capricious standard. *See Universal Camera Corp. v. Nat’l Labor Relations Bd.*, 340 U.S. 474, 477 (1951); *Union Oil Co. of Cal. v. Fed. Power Comm’n*, 542 F.2d 1036, 1040–41 (9th Cir.1976). If EPA’s determination is arbitrary and capricious, EPA cannot show it was supported by substantial evidence.

Whether a writ of mandamus should issue to put an end to an agency’s unreasonable delay is reviewed under the factors established by the D.C. Circuit in *Telecomm. Research & Action Ctr. v. FCC*, 750 F.2d 70, 75 (D.C. Cir. 1984) (hereinafter “*TRAC*”); *see In re A Community Voice*, 878 F.3d 779 (9th Cir. 2017).

ARGUMENT

I. EPA EXCEEDED ITS STATUTORY AUTHORITY AND ACTED CONTRARY TO ITS SCIENTIFIC FINDINGS IN DENYING THE 2007 PETITION.

The FFDCA constrains EPA’s discretion. It prohibits EPA from taking

actions that endanger food safety and expose children to dangerous pesticides whenever EPA finds a pesticide unsafe or is unable to make an affirmative safety finding. The Pruitt Order blatantly defies these statutory mandates and disregards years of EPA scientific findings that have progressively grown in linking low-level chlorpyrifos exposures with serious brain damage to children.

A. EPA Lacks the Statutory Authority To Maintain Chlorpyrifos Tolerances in the Absence of an Affirmative Finding that Chlorpyrifos Is Safe.

Administrator Pruitt violated the law by leaving chlorpyrifos tolerances in place. Under the FFDCA, the EPA Administrator “may establish or leave in effect a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the tolerance is safe.” 21 U.S.C. § 346a(b)(2)(A)(i); *see also id.* § 346a(b)(2)(A)(i) (“The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.”). FFDCA leaves EPA no discretion to define “safe.” It defines “safe” to mean the Administrator has determined there is a reasonable certainty of no harm from aggregate exposures to the pesticide chemical residue. *Id.* § 346a(b)(2)(A)(ii).

Previously, in proposing to revoke all chlorpyrifos tolerances, EPA articulated the controlling legal standard, stating “because the FFDCA is a safety standard, EPA can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe.” ER 1133; *accord* ER 1134 (“EPA may establish or leave

in effect a tolerance for pesticide only if it finds that the tolerance is safe”). EPA again acknowledged the operative standard when it reaffirmed its proposal to revoke the tolerances in 2016. ER 1291 (“EPA can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe.”).

The legal standard is purged from the Pruitt Order. Nowhere does that Order acknowledge EPA’s legal obligation to make an affirmative safety finding in order to retain chlorpyrifos tolerances. Nor does it purport to make a finding that chlorpyrifos is safe. And yet the Pruitt Order denied the 2007 Petition and left chlorpyrifos tolerances in place for five or more years. It did not withdraw the proposed rule or change its findings, but left it in legal limbo. The Pruitt Order reads as if EPA has discretion to leave tolerances in place in the face of findings that the pesticide is unsafe when the Administrator prefers to engage in further review of the science.

The FFDCA forecloses this course of action. If the Administrator has made no affirmative safety finding, he lacks authority to maintain the tolerances. This case is analogous to *Massachusetts v. EPA*, 549 U.S. 497, 533 (2007), where the Supreme Court held that the Clean Air Act authorized EPA to avoid taking regulatory action to limit greenhouse gas emissions from motor vehicles only if it determined that greenhouse gases do not contribute to climate change. EPA could not refuse to regulate for policy reasons unrelated to the scientific issue of

endangerment. *Id.* at 533-34.

Similarly, EPA lacks the authority to make tolerance decisions based on factors other than food safety. Nonetheless, the Pruitt Order cites the widespread use of chlorpyrifos as a reason to engage in further study before removing it from the market. 82 Fed. Reg. at 16,590. Congress decided long ago that the safety of our food cannot be sacrificed, *see Nat'l Coalition Against Misuse of Pesticides v. Thomas*, 809 F.2d 875, 881-83 (D.C. Cir. 1987) (EPA acted arbitrarily and capriciously in relying exclusively on foreign economic impacts in raising a tolerance), and in 1996, explicitly made safety the sole determinant. 21 U.S.C. § 346a(b)(2)(A)(i)-(ii); *see Whitman v. American Trucking Assoc.*, 531 U.S. 457, 468 (2001) (EPA needs, but lacks, textual authority to consider costs or implementation burdens in setting air pollution standards); *State Farm*, 463 U.S. at 43 (agency cannot base its decision “on factors which Congress has not intended it to consider”). The Administrator acted in blatant violation of FFDCA by denying the 2007 Petition and leaving chlorpyrifos tolerances in place without determining that the pesticide is safe.

B. EPA’s Findings that Chlorpyrifos Is Unsafe Compel It To Revoke the Tolerances.

It is well-settled that an agency “must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.” *State Farm*, 463 U.S. at 43. Courts

have applied this rule to prevent EPA from making tolerance determinations at odds with its safety findings. *See Nat'l Corn Growers Assoc. v. EPA*, 613 F.3d 266, 275 (D.C. Cir. 2010) (arbitrary and capricious for EPA to revoke import tolerances when EPA found exposure to the pesticide from imported foods safe); *Nat'l Coalition*, 809 F.2d at 875 (EPA acted arbitrarily when it had no scientific basis for changing a zero tolerance into one permitting residues).

The Pruitt Order is wholly at odds with EPA's repeated findings, growing in strength over the years, that chlorpyrifos is unsafe. EPA's 2014 revised risk assessment found chlorpyrifos unsafe due to drinking water contamination, ER 231-32, 78-79, and it proposed to revoke all tolerances in 2015 because "EPA cannot determine that current dietary exposures to chlorpyrifos are safe." ER 1159; *see id.* ("EPA cannot find that any current tolerances are safe and is therefore proposing to revoke all chlorpyrifos tolerances"); ER 1150 ("food exposures, when aggregated with residential exposures and potentially more significant drinking water exposures do present a significant risk concern and support revocation of all chlorpyrifos tolerances").¹¹

¹¹ The Pruitt Order engages in revisionist history when it recharacterizes the proposed revocation as based on uncertainty surrounding neurodevelopmental harm. ER 27, 34.

EPA and SAP have repeatedly found that using 10% cholinesterase inhibition as the regulatory endpoint, as the 2014 risk assessment does, fails to protect children from brain damage associated with lower exposures. ER 853 (2012 EPA analysis) ER 956 (2012 SAP report); ER 184 (2014 Risk Assessment); ER 1132 (proposed tolerance revocation); ER 1191, 1225-26 (2016 SAP). In its 2016 update to its risk assessment, EPA heeded the SAP's advice and reconstructed the exposures in the Columbia study at which learning disabilities occurred and found chlorpyrifos unsafe in virtually any way that people are exposed to it. ER 1271. In addition to unsafe drinking water exposures, EPA found unsafe food exposures, with the most exposed population – children 1-2 years of age – exposed to 140 times safe levels, and unsafe exposures from pesticide drift 300 or more feet from where the pesticide is sprayed. ER 1254-55, 1271-72, 1279-83. According to EPA's Federal Register notice reiterating its proposal to revoke chlorpyrifos tolerances, "[t]he revised analysis indicates that expected residues of chlorpyrifos on most individual food crops exceed the 'reasonable certainty of no harm' safety standard" and "the majority of estimated drinking water exposures from currently registered uses, including water exposures from non-food uses, continue to exceed safe levels even taking into account more refined drinking water exposures." ER 1291; *see id.* ("the risk from the potential aggregate exposure does not meet the FFDCA safety standard").

By issuing an order maintaining chlorpyrifos tolerances in the face of these findings, EPA acted contrary to the evidence. EPA made no mention of these relevant, indeed pivotal, findings, let alone make a rational connection between them and the decision to retain chlorpyrifos tolerances. The Pruitt Order is the epitome of arbitrary and capricious decision-making whether cast as failing to consider relevant factors, acting contrary to the findings in the record, or lacking a rational justification connecting the action to such findings.

The Pruitt Order scenario resembles *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286 (D.C. Cir. 2000), where EPA had a 1998 deadline to set a maximum contaminant level goal under the Safe Drinking Water Act for drinking water disinfectant byproducts like chloroform. In 1994, EPA proposed a goal of zero based on its finding that any level of exposure could cause cancer. *Id.* at 1287. Subsequently, EPA found that chloroform likely causes human cancers only above a certain dose, yet it set a goal of zero because it wanted to engage in additional scientific review, including with its scientific advisory committee. *Id.* at 1288. The court held that EPA cannot act contrary to the best available scientific evidence at the time of its decision “simply because of the possibility of contradiction in the future by evidence unavailable at the time of action – a possibility that will *always* be present.” *Id.* at 1290-91 (emphasis in original).

Chlorine Chemistry Council rejected EPA’s contention that the risk

assessment at issue did not represent its ultimate conclusion, calling “these semantic somersaults pointless.” 206 F.3d at 1291. As the court explained, “[a]ll scientific conclusions are subject to some doubt; future hypothetical findings always have the potential to resolve the doubt (the new resolution itself being subject, of course, to falsification by later findings)”. *Id.*

As in *Chlorine Chemistry Council*, EPA made safety finding in its risk assessments, which is how EPA makes tolerance determinations and it has made no superseding agency findings. In the face of EPA’s findings that chlorpyrifos is unsafe in every way that people are exposed to it, the Administrator must revoke the tolerances. *Id.* On this record, granting the Petition and revoking all chlorpyrifos tolerances is the only legally defensible course of action.

C. A Desire to Continue Studying the Science Is Not a Legally Permissible Reason To Leave Chlorpyrifos Tolerances in Place.

The Pruitt Order’s primary justification for failing to revoke chlorpyrifos tolerances is: “EPA’s preference is to fully explore approaches raised by the SAP and commenters on the proposed rule, and possibly seek additional authoritative peer review of EPA’s risk assessment prior to finalizing any regulatory action in the course of registration review.” ER 34. In alluding generally to scientific uncertainties, the Pruitt Order ignores how much progress has been made in assessing the large body of scientific evidence of neurodevelopmental harm from chlorpyrifos. EPA extensively reviewed chlorpyrifos and sought review by the

SAP three times. Each review found that chlorpyrifos damages children's developing brains at exposures far lower than EPA's regulatory endpoint. ER 785-86, 817-18 (2008 SAP); ER 971, 973 (2012 SAP); ER 224-26, 229 (2014 Assessment); ER 1191, 1198, 1225 (2016 SAP). As the reviews progressed and further studies were published, the degree of uncertainty diminished to the point that EPA concluded that the human population studies more likely underestimated, rather than over-estimated the correlation. ER 923, 927, 951-52 (EPA 2012 comprehensive analysis).

While there is some scientific uncertainty as to the precise level of exposure that damages children's brains, both EPA and the SAP have found with confidence for many years that children are at risk at levels of exposure far below what EPA currently allows. This uncontested fact has led EPA to find chlorpyrifos unsafe. The Pruitt Order's invocation of scientific uncertainty rings hollow given the overwhelming scientific evidence and the unbroken EPA and SAP findings.

Scientific uncertainty offers no excuse for the Pruitt Order unless it is grounded in EPA's obligations under the underlying statute. The Supreme Court reversed EPA's inaction under the Clean Air Act in *Massachusetts v. EPA* with an admonition that EPA cannot

avoid its statutory obligation by noting the uncertainty surrounding various features of climate change and concluding that it would therefore be better not to regulate at this time. . . . If the scientific uncertainty is so profound that it precludes EPA from making a reasoned judgment as to whether

greenhouse gases contribute to global warming, EPA must say so. That EPA would prefer not to regulate greenhouse gases because of some residual uncertainty. . . is irrelevant.

549 U.S. at 533-34.

Here, Congress established a statutory standard that precludes delaying protection, particularly to children, due to scientific uncertainty when there is evidence of harm. Under the food safety standard, uncertainty compels revocation of tolerances since “safe” means that EPA “has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue,” 21 U.S.C. § 346a(b)(2)(A)(ii), and EPA can “leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe.” *Id.* § 346a(b)(2)(A)(i). If uncertainty prevented the Administrator from making an affirmative safety finding, his only option was to revoke the tolerances. This is in keeping with the longstanding burden of proving safety on EPA and industry groups seeking to retain food tolerances. *See Env'tl. Def. Fund, Inc. v. U.S. Dep't of Health, Ed. & Welfare*, 428 F.2d 1083, 1092 n.27 (D.C. Cir. 1970) (burden of producing scientific data establishing safety is on those seeking to permit the residue).

Other statutory provisions prescribe how EPA must deal with scientific uncertainty. EPA must act on the basis of available information on the special susceptibility of infants and children, including neurological differences between

adults and infants and children, and EPA must apply an additional tenfold margin of safety to account for gaps in data or evidence of pre- or post-natal toxicity to children. 21 U.S.C. § 346a(b)(2)(C). Congress specifically directed EPA to assume that children face a ten times greater risk than adults unless it has reliable data showing a different margin will be safe for infants and children. *Nw. Coal. for Alts. to Pesticides*, 544 F.3d at 1046. As required, EPA retained the FQPA tenfold safety factor because of gaps in scientific information on the mode of action and exposure levels by which chlorpyrifos causes damage to children's brains.

Any uncertainties go to the precise exposure level or additional safety factors to use in establishing a regulatory endpoint that will protect children's brains. Such uncertainty offers no reason to retain tolerances. In 2014, even using an acute poisoning endpoint, EPA found chlorpyrifos unsafe due to drinking water contamination. When it developed a regulatory endpoint that would protect children's brains, it found chlorpyrifos unsafe every way people are exposed to it. More study will simply confirm how hazardous and devastating this pesticide can be. Congress decided not to expose children to such risks by precluding EPA from maintaining tolerances when it cannot find a reasonable certainty of no harm from the pesticide.

D. The Deadline for Completing Registration Review Is Not a License To Deny the Petition and Maintain Tolerances for Unsafe Pesticides.

The Pruitt Order claims that a new administration's prerogative to re-order priorities set by prior administrations allows EPA to issue an order keeping chlorpyrifos tolerances for five or more years until it completes its registration review of chlorpyrifos. ER 34; *see* 7 U.S.C. § 136a (g)(1)(A)(iii)(I) (registration review deadline). The fact that Congress established an October 1, 2022, deadline for EPA to complete registration review of all older pesticides is no license for EPA to deny the 2007 Petition and maintain chlorpyrifos tolerances without the ability to make the requisite safety finding.

Indeed, the registration review provision states that “[n]othing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide . . .” 7 U.S.C. § 136a(g)(1)(C). This clause prohibits EPA from invoking the registration review deadline to forestall other legally required or scientifically compelled regulatory action.¹²

EPA's review of chlorpyrifos has proceeded to a point of no return. The agency has completed human health risk assessments and found chlorpyrifos

¹² FIFRA establishes the registration review process to examine all uses of a pesticide, not only food uses, but also risks to wildlife, waterbodies, and workers. While EPA accelerated the chlorpyrifos food safety determination, other FIFRA assessments and decisions remained subject to the 2022 registration review deadline.

unsafe due to drinking water contamination in 2014 and 2015, *see, e.g.*, ER 1131, and it subsequently expanded the finding that chlorpyrifos is unsafe to every way people are exposed. ER 1291. The law is clear. EPA can leave food tolerances in place only if it can find the pesticide safe. The generally applicable registration review timeline does not over-ride this specific prohibition.

In claiming the authority to postpone revoking chlorpyrifos tolerances despite its own scientific findings, EPA cites the prerogative of a new presidential administration to make policy choices that differ from its predecessor, citing *Fed. Commc'n Comm'n v. Fox Television Stations*, 556 U.S. 502 (2009). ER 33. *Fox Television*, however, requires agencies to provide a reasoned explanation for such reversals that comports with *State Farm* and a more detailed explanation when it contradicts prior factual findings and circumstances that underlay or were engendered by the earlier agency decision. 556 U.S. at 515-16.

EPA reversed course without addressing its prior factual findings and the circumstances that undergirded the proposed revocation and timeline for the final rule. The salient facts and circumstances include EPA's prioritization of registration review of chlorpyrifos because of the need to respond to the 2007 Petition and address the weighty health issues it presented, 80 Fed. Reg. at 69,082, EPA's repeated findings that chlorpyrifos is unsafe, this Court's conclusion that "considerable human health interests [are] prejudiced by the delay," 798 F.3d at

814, and EPA's acknowledgment that "because the FFDCA is a safety standard, EPA can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe." ER 1131 (proposed revocation rule); *accord* ER 1291 (reaffirming and seeking further comment on the proposed revocation rule).

The Pruitt Order addresses none of these. As demonstrated above, EPA has failed to explain how it can retain chlorpyrifos tolerances in the absence of a safety finding and in the face of its repeated findings that chlorpyrifos is unsafe. EPA did not disavow EPA's previous findings that chlorpyrifos is unsafe. The Pruitt Order makes no mention of these findings, let alone make any attempt to provide a reasoned explanation for acting contrary to them. Under *Fox Television*, silence is not an option. *See Encino Motorcars v. Navarro*, 136 S. Ct. 2117, 2127 (2016). As this Court held in *Organized Village of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 968-69 (9th Cir. 2015) (en banc), "[e]lections have policy consequences. But *State Farm* teaches that even when reversing a policy after an election, an agency may not simply discard prior factual findings without a reasoned explanation." Whatever leeway a new administration has to make its own policy choices does not extend to acting in blatant disregard of the agency's previous factual determinations, like EPA's findings that chlorpyrifos is unsafe. Nor does that latitude allow the new administration to break the law by leaving tolerances in place in the face of findings of such serious harm to children.

II. THIS COURT HAS JURISDICTION TO REVIEW THE SUBSTANCE OF THE PRUITT ORDER.

While the motions panel denied EPA's motion to dismiss for failure to exhaust administrative remedies, LULAC addresses the issue because it goes to jurisdiction. This Court has jurisdiction to hear this case under the FFDCA and should waive statutory exhaustion. In the alternative, this Court has jurisdiction under FIFRA because meaningful and timely review is not obtainable under the FFDCA.¹³

A. This Court Should Waive Exhaustion and Hear this Case under the FFDCA.

The FFDCA establishes an administrative objections process and provides for judicial review at the culmination of that process. The Supreme Court and this Court have excused compliance with statutory exhaustion procedures when, as here, pursuing them would be futile and would allow an agency to violate clear statutory prohibitions.

¹³ Petitioners have standing because eliminating harmful exposures to chlorpyrifos furthers the organizations' missions and they have members who have been and will continue to be exposed to chlorpyrifos as a result of the Pruitt Order. Declarations of Brent Wilkes, Hector Sanchez, Mark Magaña, Erik Nicholson, Ramon Ramirez, Margaret Reeves, Jennifer Sass, Elena Rios, Virginia Ruiz, Anne Katten, Eugenia Economos, Maureen Swanson, Esteban Ortiz, Sylvia Youngblood, Martha Moriarty, Jaime Estrada, Beverly Johns, Diana Perez, Monica Ramirez, Javier Ceja, Amadeo Sumano, Jose Cruz, Gerardo Rios, Ofelia Aguilar, Judy Fishman, Sharon Bolton, Bonnie Wirtz; *see Friends of the Earth v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 180-81 (2000); *Citizens for Better Forestry v. U.S. Dep't of Agric.*, 341 F.3d 961, 969 (9th Cir. 2003).

1. *The Exhaustion and Judicial Review Provisions*

Within 60 days of an order by the Administrator denying a petition to establish, modify, or revoke tolerances, any person may file objections with the Administrator presenting grounds for a different outcome that were not already presented in comments. 21 U.S.C. § 346a(g)(2)(A). The objections may seek an evidentiary hearing on factual issues, *id.* § 346a(g)(2)(B), but neither LULAC nor the State Objectors sought an evidentiary hearing because their objections raise purely legal questions.

“As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each objection. . . .” *Id.* § 346a(g)(2)(C). Any person adversely affected may obtain judicial review in the court of appeals. *Id.* § 346a(h)(1).

2. *The FFDCA’s exhaustion procedure is, like that of most statutes, non-jurisdictional and subject to waiver.*

As the Supreme Court established in *Weinberger v. Salfi*, 422 U.S. 749, 764-66 (1975), statutory exhaustion requirements may be waived on equitable grounds unless they are central to the grant of subject matter jurisdiction. Even where an exhaustion requirement is stated in mandatory terms, it is rarely jurisdictional. *See, e.g., Reed Elsevier v. Muchnick*, 559 U.S. 154, 163-66 (2010) (jurisdiction over unregistered copyright despite provision stating “no civil action for infringement of the copyright in any United States work shall be instituted until the preregistration

or registration of the copyright has been made”); *Bethesda Hosp. Ass’n v. Bowen*, 485 U.S. 399, 403-05 (1988) (Medicare provider can obtain hearing over reimbursement without obtaining review by a fiscal intermediary even though the statute provided for a hearing when dissatisfied with a final determination of such a fiscal intermediary regarding the reimbursement).

The Supreme Court has distinguished federal court jurisdiction in administrative cases from the elements of the claim for relief. *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 513-14 (2006). “Claim-processing rules,” like filing deadlines and exhaustion procedures, speak to the obligations of litigants, not the power of the court, and are rarely jurisdictional. *Id.* at 513-16; *see Reed Elsevier*, 559 U.S. at 161; *Henderson v. Shinseki*, 562 U.S. 428, 434-35 (2011).

In keeping with this direction, this Court has repeatedly held that exhaustion requirements are not jurisdictional even under statutes using what looks like mandatory exhaustion language. *See, e.g., Anderson v. Babbitt*, 230 F.3d 1158, 1162 (9th Cir. 2000) (“[n]o decision which at the time of its rendition is subject to appeal to the Director or an Appeals Board shall be considered final so as to be agency action subject to judicial review under 5 U.S.C. §704.”); *Rumbles v. Hill*, 182 F.3d 1064, 1067 (9th Cir. 1999) (“[n]o action shall be brought . . . until such administrative remedies as are available are exhausted”).

Admittedly, in holding that EPA has done what this Court ordered it to do in

an earlier mandamus action, this Court stated that “[n]ow that EPA has issued its denial, substantive objections must first be made through the administrative process mandated by statute.” *In re PANNA*, 863 F.3d 1131, 1132 (9th Cir. 2017). The Court was distinguishing between the timing of EPA’s action and a challenge to its substance. The Court recited the exhaustion provisions without applying *Weinberger* and its progeny to determine whether exhaustion is jurisdictional. Nor did the Court address whether, once LULAC filed objections, it would be futile to await EPA’s resolution.¹⁴ Moreover, the only case to address whether the FFDCA objection requirement is jurisdictional held that it was not. In *National Coalition*, the D.C. Circuit refused to require exhaustion under the analogous, predecessor objection provision, stating “[f]irst and foremost, the language of the specific provision on which EPA relies (§ 346a(d)(5)), is permissive, not mandatory. Where the language, as here, is clear, that should be the end of the matter.” 809 F.2d at 879.

3. *Exhaustion Should Be Waived.*

As an element of the cause of action, rather than a jurisdictional prerequisite, “[t]his court, along with every other circuit to consider the issue, has held that there is no exhaustion requirement if resort to the agency would be futile.” *SAIF*

¹⁴ *Nader v. U.S. EPA*, 859 F.2d 747 (9th Cir. 1988), also described the FFDCA’s predecessor exhaustion requirements without addressing whether they are jurisdictional.

Corp./Oregon Ship v. Johnson, 908 F.2d 1434, 1441 (9th Cir. 1990); *see McBride Cotton & Cattle Corp. v. Veneman*, 290 F.3d 973, 976 (9th Cir. 2002). Here, this Court should waive exhaustion because it would be futile and would perpetuate the legal violations and harm that Congress has prohibited.

First, the legal violation at the heart of both the objections and this case is EPA's decision to leave chlorpyrifos tolerances in place in the absence of a safety finding for five or more years. This case argues that the delay in revoking tolerances without safety findings is in flagrant violation of the law. Deferring judicial review until the Administrator rules on the objections would perpetuate EPA's illegal conduct. The Administrator violated the statutory prohibition on retaining chlorpyrifos tolerances because he preferred to continue studying the science and put off revoking the tolerances until October 1, 2022. EPA is using the objection process to accomplish this illegal outcome. In response to a request from U.S. Senators for an expeditious resolution of the objections, EPA laid out a plan to conduct another risk assessment, another proposed rule, and eventual final regulatory action over many years. Under EPA's plan, a ruling on the objections would come when EPA completes registration review of chlorpyrifos in 2021 or 2022. This course of action will deprive LULAC of any opportunity to challenge the Administrator's decision to put off regulatory action on chlorpyrifos. Using the objection process to perpetuate EPA's illegal delay renders the process a sham and

deprives LULAC of the ability to halt EPA's violation of the law. *See Pac. Mar. Ass'n v. Nat'l Labor Relations Bd.*, 827 F.3d 1203, 1211 (9th Cir. 2016) (no adequate means within petitioners' control to seek judicial review).

Second, requiring exhaustion would allow EPA to violate Congress's prohibition on maintaining pesticide tolerances without a safety finding. Whether it is legally impermissible to leave chlorpyrifos tolerances in place without a safety finding is a purely legal question that will neither be informed nor advanced by EPA's ruling on the objections in four years or more. Courts have dispensed with exhaustion when it would deny review of a claim that the agency acted in derogation of clear statutory prohibitions or in excess of its statutory authority if doing so would leave parties without recourse. *See Leedom v. Kyne*, 358 U.S. 184, 187-89 (1958) (violation of statute); *Oestereich v. Selective Serv. System Local Bd. No. 11*, 393 U.S. 233, 238 (1966) (clear departure from statutory mandate); *Chamber of Commerce of U.S. v. Reich*, 74 F.3d 1322 (D.C. Cir. 1996) (challenge to executive order's violation of statute). When an agency exceeds its statutory authority, it is the province of the courts to step in. *See Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 680 (1986) ("[w]e ordinarily presume that Congress intends the executive to obey its statutory commands and, accordingly, that it expects the courts to grant relief when an executive agency violates such a command.").

Finally, waiting for EPA to rule on the objections would continue to expose the public to risks of acute poisonings and damage to children's brains from a pesticide that EPA has found unsafe. If the Administrator had finalized the proposed revocation rule, it would have become effective at the end of September 2017, and growers would have stopped spraying foods with chlorpyrifos well before that deadline to avoid leaving residues on the food and rendering the food adulterated and subject to seizure and penalties. ER 1159 (proposed revocation rule).

Because the Administrator has no intention of ruling on the objections for years, the objections and this case present purely legal issues, and the harm Congress has forbidden is occurring, this Court should waive any exhaustion procedures and hear this case before the Administrator rules on the objections.

B. If Exhaustion Is Required, Review of the Legality of Leaving Chlorpyrifos Tolerances in Place Is Not Obtainable under the FFDCA, Giving Rise to Review under FIFRA.

If the Court determines that petitioners cannot challenge the Pruitt Order under the FFDCA before the Administrator rules on the objections, jurisdiction is available under FIFRA. 7 U.S.C. § 136n(b).¹⁵ While the FFDCA regulates

¹⁵ Under FIFRA's jurisdictional provision, 7 U.S.C. § 136n(b), parties to administrative proceedings may obtain judicial review of EPA orders issued after a hearing in the court of appeals. LULAC participated in the administrative process by submitting public comments. *See, e.g.*, ER 1391-1513, 1529-54, 1716-1783; *see United Farm Workers v. Adm'r, Envtl. Prot. Agency*, 592 F.3d 1080, 1082 (9th

residues of pesticides on food, FIFRA regulates use of pesticides. In order to register or maintain a registration for a pesticide under FIFRA, EPA must find the pesticide will not generally cause “unreasonable adverse effects on the environment.” 7 U.S.C. §136a(c)(5); *see also id.* §136d(b) (providing for cancellation of registrations of pesticides that pose unreasonable adverse effects). FIFRA defines “unreasonable adverse effects” to include “a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under the FFDCA.” 7 U.S.C. §136(bb). The Pruitt Order leaves chlorpyrifos tolerances and registrations in place, even though chlorpyrifos poses human dietary risks that are inconsistent with the safety standard. In doing so, the Pruitt Order violates FIFRA.

In keeping with the presumption in favor of judicial review of agency action, the FFDCA requires adherence to its objection procedure only when review of an issue would be obtainable through that route. It provides that “[a]ny issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law.” *Id.* §346a(h)(5).¹⁶ If this Court

Cir. 2010) (public comment period is a “hearing” under § 136n(b)).

¹⁶ This standard furthers the presumption in favor of judicial review and is analogous to the APA, which authorizes review where there is no other adequate remedy at law and where no statute expressly precludes review. In recent years, the Supreme Court has rejected wooden interpretations of statutory review provisions that would deny litigants review of actions having direct and

holds that judicial review under 21 U.S.C. § 346a(h) must wait until the Administrator rules on the administrative objections, meaningful and timely judicial review of the Pruitt Order's violation of the FIFRA prohibition on registering a pesticide that runs afoul of the FFDCA's safety standard, and therefore would be appropriate under FIFRA.

In *Nat. Res. Def. Council v. Johnson*, 461 F.3d 164, 176 (2d Cir. 2008), the Second Circuit held that 21 U.S.C. § 346a(h)(5) precluded judicial review under FIFRA of issues that could be fully reviewed under the FFDCA; the jurisdictional defect arose because the case had been brought in district court, rather than the court of appeals. The *NRDC* petitioners never argued, nor was there any indication, that submitting, and waiting for EPA to rule on, objections would be futile. Nor was EPA keeping tolerances in place in the face of agency findings that the “human dietary risk from residues” are “inconsistent with” the food safety standard, making the pesticide ineligible for FIFRA registration.¹⁷ If this Court holds that LULAC cannot obtain judicial review under the FFDCA until EPA rules

appreciable legal consequences. See *Sackett v. EPA*, 566 U.S. 120 (2012); *U.S. Army Corps of Engineers v. Hawkes Co., Inc.*, 136 S.Ct. 1807 (2016).

¹⁷ *Nader v. EPA*, 859 F.2d 747, never addressed whether review was obtainable as required under 21 U.S.C. 346a(h)(5). Nor would review under FIFRA have been available because the FQPA amended FIFRA in 1996 to define unreasonable adverse effects to include human dietary risks prohibited under the FQPA. Pub. L. No. 104–170, August 3, 1996, 110 Stat 1489.

on the objections, judicial review of EPA's ongoing violation would be unobtainable under the FFDCA and therefore appropriate under FIFRA.

III. IF THIS COURT DETERMINES IT LACKS JURISDICTION, IT SHOULD ISSUE A WRIT OF MANDAMUS DIRECTING EPA TO DECIDE LULAC'S OBJECTIONS WITHIN 60 DAYS.

This case follows a series of unreasonable delay cases that culminated in this Court's finding that EPA's delay in acting on the 2007 Petition was "egregious." *In re PANNA*, 798 F.3d at 811. This Court held EPA's delay unreasonable after EPA found that chlorpyrifos damages children's brains at low-level exposures, is unsafe in drinking water, and poses unacceptable risks to the workers who apply it to or harvest our food. *Id.* at 814

While EPA met this Court's deadline for issuing a decision on the Petition, that decision postpones revoking chlorpyrifos tolerances or taking other regulatory action for five years or longer. Additionally, EPA now plans to delay ruling on the objections until after it engages in up to five more years of study and regulatory proceedings. And so EPA's record of unreasonable delay continues.

To determine whether an agency has unreasonably delayed taking agency action, this Court applies the six-factor balancing test set out by the D.C. Circuit in *TRAC*:

- (1) the time agencies take to make decisions must be governed by a "rule of reason";
- (2) where Congress has provided a timetable or other indication of the speed

with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason;

- (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake;
- (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority;
- (5) the court should also take into account the nature and extent of the interests prejudiced by the delay; and
- (6) the court need not “find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed.”

TRAC, 750 F.2d at 80.

A. EPA’s Plan To Postpone Action for Five Years Violates the Rule of Reason (Factor 1).

Unreasonable delay cases generally begin by assessing the length of the delay. If measured from when the objections were filed, the delay to date has been relatively short. However, the current delay builds upon delay this Court called “unreasonable” and “egregious,” which spanned nearly ten years and ended only because this Court ordered EPA to act on the 2007 Petition by specific deadlines.

A delay is unreasonable if it is “tantamount” or “equivalent to a final denial” and is inflicting harm the agency is charged with avoiding. *Pub. Citizen Health Research Grp. v. Comm’r, Food & Drug Admin.*, 740 F.2d 21, 32, 35 (D.C. Cir. 1984). EPA’s “action” is not the action compelled by the law, but a refusal to take that action for five or more years. The Pruitt Order denied the Petition because EPA chose to engage in further study and put off acting on the proposed revocation

until October 1, 2022, the general registration review deadline for older pesticides. EPA recently unveiled a course of action in which it will revise its chlorpyrifos risk assessment, seek public comment, propose another regulatory action and seek another round of comment, and eventually take final regulatory action on chlorpyrifos and rule on the administrative objections by that same 2022 deadline. Ordonia Exh. F. In other words, EPA has made taking final regulatory action on chlorpyrifos synonymous with deciding the administrative objections.

“The reasonableness of the delay must be judged ‘in the context of the statute’ which authorizes the agency’s action.” *Pub. Citizen Health Research Grp. v. Aucter*, 702 F.2d 1150, 1158 n.30 (D.C. Cir. 1983). The FFDCA prohibits maintaining tolerances for pesticides without a safety finding or in the face of findings that the pesticide is unsafe. EPA has completed the resource-intensive task of conducting risk assessments and making findings that chlorpyrifos is unsafe. All that remains to be done is taking the congressionally mandated action of revoking the tolerances. Delaying revocation of chlorpyrifos tolerances and ruling on the objections for five or more years is unreasonable in light of Congress’s mandate to protect children and EPA’s history of egregious delay. Any “claim of premature rulemaking has come and gone,” as this Court held in *In re PANNA*, 840 F.3d 1014 (9th Cir. 2016).

B. The Statutory Scheme Calls for Speedy Action (Factor 2).

In addition to its strong mandates to protect our food and children's health, the FFDCA evinces Congress's intent that EPA act expeditiously when it has such strong evidence a pesticide is unsafe. EPA has a mandatory duty to act on the objections and to do so "as soon as practicable." 21 U.S.C. § 346a(g)(2)(C).

While EPA may conduct an evidentiary hearing to resolve factual issues, the objections raise the same purely legal questions presented in this case and do not seek an evidentiary hearing. It should take months, but certainly not years, for EPA to decide what action to take on the objections, particularly given that the FFDCA constrains EPA's discretion and mandates tolerance revocation.

If judicial review must await EPA's decision on the objections, EPA's inaction leaves LULAC "stuck in administrative limbo; it enjoys neither a favorable ruling on its petition nor the opportunity to challenge an unfavorable one." *In re People's Mojahedin Organization of Iran*, 680 F.3d 832, 837 (D.C. Cir. 2012) (delay in resolving petition for revocation of terrorist listing insulated decision from judicial review); *see also In re American Rivers*, 372 F.3d 413, 420 (D.C. Cir. 2004) (judicial intervention to end FERC's "marathon round of administrative keep-away").

C. The Health Risks and Prejudice They Cause Make the Delay Unreasonable (Factors 3 and 5).

It is well-settled that "[w]hen the public health may be at stake, the agency

must move expeditiously to consider and resolve the issues before it.” *Pub. Citizen Health Research Grp.*, 740 F.2d at 34-35. EPA has denied people protection from chlorpyrifos, despite finding it unsafe in food, drinking water, and pesticide drift because it poses unacceptable risks of pesticide poisonings and learning disabilities in children. It made these findings for drinking water in 2014, along with findings that workers are exposed to unsafe exposures. ER 194-96, 271-73, 276-78, 285-90. The delay has become only more serious and indefensible as EPA strengthened its findings that chlorpyrifos damages children’s brains every way children are exposed to the pesticide. ER 1254-55, 1271-72, 1279-82.

The Pruitt Order purports to seek greater scientific certainty as to the magnitude of the risks of neurodevelopmental harm before taking regulatory action. This is an insufficient reason to delay as a matter of fact since, even without protecting children against such harm, EPA found chlorpyrifos unsafe in drinking water, and the correlation between low-level exposures and damage to children’s brains is well-established in a robust body of scientific literature and findings by EPA and its SAP. *See supra* at 13-21. It is also insufficient as a matter of law as “[t]he risk to human life need not be a certainty to justify expedition [of agency action].” *Pub. Citizen Health Research Grp.*, 702 F.2d at 1158 n.26.

When the agency’s review has spanned years and progressed to the extent it has here, “scientific uncertainties and technical complexities, while no doubt

considerable, can no longer justify delay.” *Pub. Citizen Health Research Grp. v. Chao*, 314 F.3d 143, 156 (3d Cir. 2002).

As this Court previously found, “considerable human health risks” caused by exposure to chlorpyrifos are “prejudiced by the delay,” *In re PANNA*, 798 F.3d at 814, and favor mandamus relief. That harm takes two forms.

First, every year, chlorpyrifos causes acute poisonings that make people sick with symptoms ranging from diarrhea and vomiting to seizures, fainting, and worse. Poison reporting in California and Washington regularly documents incidents associated with chlorpyrifos with pesticide drift being a frequent cause of poisonings. ER 1521-28 (Washington State poisoning incidents); ER 1483-1511 (California poisoning incidents); Reeves Decl. ¶¶ 7-12; Katten Decl. ¶¶ 10-12. In one incident in May 2017, chlorpyrifos traveled one-half mile from a farm, sickening dozens of people and leading to a fine exceeding \$30,000. Reeves Decl. ¶ 27; Katten Decl. ¶ 11.

Second, low-level exposures to chlorpyrifos damage the developing brains of children, leading to the kinds of learning disabilities that plague one in six children in the United States. Swanson Decl. ¶ 6. Learning disabilities impede the ability of children to achieve their potential and take their toll on families, schools, social services, and health care systems. Moriarty Decl. ¶¶ 2-3; Youngblood Decl. ¶¶ 4-6. For example, it costs as much on average to educate children with learning

disabilities, and one third of children in the U.S. juvenile justice system have one or more learning or behavioral disorders. Swanson Decl. ¶ 8; ER 1811-12 (studies estimating economic losses from reduced IQ and learning disabilities).

As long as EPA allows chlorpyrifos to be sprayed on our food, people will be unable to prevent exposures to chlorpyrifos and the risk of harm. People cannot avoid chlorpyrifos when it contaminates their drinking water. ER 276-79 (2014 Risk Assessment) (drinking water monitoring confirms chlorpyrifos is unsafe); AR 2136 (California water monitoring detected chlorpyrifos in 17.7% of samples, with 9.9% exceeding the state's concentration limit).

Nor can they avoid it in food given its widespread use and pervasive residues. In food sampling in 2015, the U.S. Department of Agriculture detected chlorpyrifos on 12 different types of fruits and vegetables, including on fruits like peaches, nectarines, grapes, and strawberries that are popular with children. Sass Decl. ¶¶ 39-41. Apples, the top fruit consumed by children, have residues even after they are washed, and chlorpyrifos residues persist on citrus and melons even after they are washed and peeled. Sass. Dec. ¶ 40.

Chlorpyrifos also makes its way into our air when it travels windborne from where it is sprayed to schools, day cares, and homes. In 2016, EPA found unsafe exposures in air monitoring of chlorpyrifos. ER 1279-82. In California, air monitoring showed chlorpyrifos as having one of the highest number of detections

in 2011-2015, and in 2015, 61% of the air samples taken at a high school detected chlorpyrifos. ER 131-32. EPA found in its 2016 risk assessment that people are exposed to unsafe chlorpyrifos levels more than 300 feet from where it is applied, much further than the buffers EPA required in 2012 to reduce exposures from spray drift, ER 1254, 1278-80, and poisoning reports and a recent evaluation by the California Department of Pesticide Regulation confirm that chlorpyrifos drifts in toxic amounts at greater distances. ER 1521; Katten Decl. ¶ 11; Sass Decl. ¶ 49; Reeves Decl. ¶ 26 (California draft evaluation of chlorpyrifos for designation as a toxic air contaminant). Farmworker children are also exposed to chlorpyrifos when their parents track residues home on their shoes and clothing. ER 1447-48; ER 1680-1710.

Not only is chlorpyrifos making its way into our food, drinking water, and air, but it is also already in our bodies. Center for Disease Control monitoring through urine testing reveals that members of the U.S. population – across all ages, sex and ethnicities – carry chlorpyrifos metabolites in their bodies. Reeves Decl.

¶¶ 16, 28.¹⁸

¹⁸ When this Court issued a writ of mandamus in 2015, it referenced the risks to farmworkers from many activities performed in the field. 798 F.3d at 814. EPA's 2016 risk assessment finds farmworkers are exposed to unsafe levels of chlorpyrifos from all handling activities and field work. ER 1284-86. In addition, NOAA Fisheries recently released a biological opinion finding that chlorpyrifos is likely to jeopardize the survival and recovery and adversely modify the critical habitat of all 28 Pacific salmon and steelhead populations on the Endangered

Chlorpyrifos is ubiquitous and impossible to avoid, making EPA's delay and exposure of children to risks of brain damage unconscionable. "Lack of alternative means of eliminating or reducing the hazard necessarily adds to unreasonableness of a delay." *See Cutler v. Hayes*, 818 F.2d 879, 898 (D.C. Cir. 1987).

D. No Competing Priorities Justify EPA's Delay (Factor 4).

EPA would be hard pressed to offer other higher priorities that could justify delaying taking regulatory action on chlorpyrifos. Congress made protecting children the highest of priorities when it adopted the health-based mandates in the FQPA.

EPA recently identified several deregulatory and delay actions that it is undertaking that will weaken public health protections from toxic pesticides like chlorpyrifos. Ordonia Exh. F. Complying with the congressional mandate to revoke tolerances for unsafe pesticides takes precedence over discretionary actions to weaken public health safeguards.

E. EPA Appears to be Delaying for Improper Reasons (Factor 6).

While the Court need not find any impropriety "lurking behind EPA's lassitude" to grant mandamus relief, *TRAC*, 750 F.2d at 80, it appears that EPA

Species Act list, necessitating substantial changes to allowable uses of chlorpyrifos in salmon habitat.

https://earthjustice.org/sites/default/files/files/Final%20BiOp_Chlorpyrifos.compressed.pdf.

denied the Petition for improper reasons. EPA staff, after a decade of review, drafted a final revocation rule based on EPA's findings. Less than a month before the court-ordered deadline, political aides to the new Administrator directed staff to reverse course and draft a denial order. Exh. B at 12, 17; Exh. C at 1-2. The Pruitt Order and EPA's press release highlight the widespread use and agricultural community's desire to retain chlorpyrifos, factors that cannot lawfully be the basis for tolerance decisions. *Id.* at 43; 82 Fed. Reg. at 16,590.

In sum, under the *TRAC* factors, EPA's delay in ruling on the objections is unreasonable. It is appropriate for this Court to issue another writ of mandamus, ordering EPA to decide the objections within 60 days, and "let [the] agency know, in no uncertain terms, that enough is enough." *Pub. Citizen Health Research Grp. v. Brock*, 823 F.2d 626, 627 (D.C. Cir. 1987).

CONCLUSION

This Court should hold that Administrator Pruitt exceeded his authority and acted contrary to the FFDCA and the record in denying the 2007 Petition and remand with directions to revoke all tolerances and cancel all registrations within 60 days. In the alternative, if the Court decides it lacks jurisdiction to review the substance of the Pruitt Order, it should issue a writ of mandamus directing Administrator Pruitt to rule on the objections within 60 days.

/s/Patti A. Goldman

PATTI A. GOLDMAN

MARISA C. ORDONIA

KRISTEN L. BOYLES

Earthjustice

705 Second Avenue, Suite 203

Seattle, WA 98104

(206) 343-7340 | Phone

(206) 343-1526 | Fax

pgoldman@earthjustice.org

mordonia@earthjustice.org

kboyles@earthjustice.org

Attorneys for Petitioners

STATEMENT OF RELATED CASE

This case is related to *In re PANNA v. EPA*, No. 14-72794, because the two cases raise the same or closely related issues and involve the same events, namely EPA's failure to ban chlorpyrifos in response to the 2007 Petition. This case also is a comeback case within the meaning of Ninth Circuit Rule 1.12. This Court previously heard *In re PANNA*, and issued a writ of mandamus directing EPA to respond to the 2007 Petition by specified deadlines. *See* Ninth Circuit Rule 28-2.6 - Statement of Related Cases. This case seeks review of EPA's 2017 denial of the 2007 Petition and, in the alternative, seeks another writ of mandamus compelling EPA to decide administrative objections forthwith.

CERTIFICATE OF COMPLIANCE

This brief complies with the length limits permitted by Ninth Circuit Rule 28.1-1. The brief is 13,956 words, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

/s/Patti A. Goldman

Patti A. Goldman

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on January 23rd, 2018.

I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Patti A. Goldman

Patti A. Goldman

ADDENDUM

STATUTES

5 U.S.C. §706

7 U.S.C. §136

7 U.S.C. §136(a)

7 U.S.C. §136(d)

7 U.S.C. §136(n)

21 U.S.C. §346a

denied on the ground that it is against the United States or that the United States is an indispensable party. The United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: *Provided*, That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance. Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 392; Pub. L. 94-574, § 1, Oct. 21, 1976, 90 Stat. 2721.)

HISTORICAL AND REVISION NOTES

<i>Derivation</i>	<i>U.S. Code</i>	<i>Revised Statutes and Statutes at Large</i>
.....	5 U.S.C. 1009(a).	June 11, 1946, ch. 324, § 10(a), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

AMENDMENTS

1976—Pub. L. 94-574 removed the defense of sovereign immunity as a bar to judicial review of Federal administrative action otherwise subject to judicial review.

§ 703. Form and venue of proceeding

The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. If no special statutory review proceeding is applicable, the action for judicial review may be brought against the United States, the agency by its official title, or the appropriate officer. Except to the extent that prior, adequate, and exclusive opportunity for judicial review is provided by law, agency action is subject to judicial review in civil or criminal proceedings for judicial enforcement.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 392; Pub. L. 94-574, § 1, Oct. 21, 1976, 90 Stat. 2721.)

HISTORICAL AND REVISION NOTES

<i>Derivation</i>	<i>U.S. Code</i>	<i>Revised Statutes and Statutes at Large</i>
.....	5 U.S.C. 1009(b).	June 11, 1946, ch. 324, § 10(b), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

AMENDMENTS

1976—Pub. L. 94-574 provided that if no special statutory review proceeding is applicable, the action for judicial review may be brought against the United States, the agency by its official title, or the appropriate officer as defendant.

§ 704. Actions reviewable

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 392.)

HISTORICAL AND REVISION NOTES

<i>Derivation</i>	<i>U.S. Code</i>	<i>Revised Statutes and Statutes at Large</i>
.....	5 U.S.C. 1009(c).	June 11, 1946, ch. 324, § 10(c), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface of this report.

§ 705. Relief pending review

When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

HISTORICAL AND REVISION NOTES

<i>Derivation</i>	<i>U.S. Code</i>	<i>Revised Statutes and Statutes at Large</i>
.....	5 U.S.C. 1009(d).	June 11, 1946, ch. 324, § 10(d), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface of this report.

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

- (1) compel agency action unlawfully withheld or unreasonably delayed; and
- (2) hold unlawful and set aside agency action, findings, and conclusions found to be—
 - (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
 - (B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

HISTORICAL AND REVISION NOTES

Derivation	U.S. Code	Revised Statutes and Statutes at Large
.....	5 U.S.C. 1009(e).	June 11, 1946, ch. 324, § 10(e), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface of this report.

ABBREVIATION OF RECORD

Pub. L. 85-791, Aug. 28, 1958, 72 Stat. 941, which authorized abbreviation of record on review or enforcement of orders of administrative agencies and review on the original papers, provided, in section 35 thereof, that: "This Act [see Tables for classification] shall not be construed to repeal or modify any provision of the Administrative Procedure Act [see Short Title note set out preceding section 551 of this title]."

CHAPTER 8—CONGRESSIONAL REVIEW OF AGENCY RULEMAKING

Sec.	
801.	Congressional review.
802.	Congressional disapproval procedure.
803.	Special rule on statutory, regulatory, and judicial deadlines.
804.	Definitions.
805.	Judicial review.
806.	Applicability; severability.
807.	Exemption for monetary policy.
808.	Effective date of certain rules.

§ 801. Congressional review

(a)(1)(A) Before a rule can take effect, the Federal agency promulgating such rule shall submit to each House of the Congress and to the Comptroller General a report containing—

(i) a copy of the rule;

(ii) a concise general statement relating to the rule, including whether it is a major rule; and

(iii) the proposed effective date of the rule.

(B) On the date of the submission of the report under subparagraph (A), the Federal agency promulgating the rule shall submit to the Comptroller General and make available to each House of Congress—

(i) a complete copy of the cost-benefit analysis of the rule, if any;

(ii) the agency's actions relevant to sections 603, 604, 605, 607, and 609;

(iii) the agency's actions relevant to sections 202, 203, 204, and 205 of the Unfunded Mandates Reform Act of 1995; and

(iv) any other relevant information or requirements under any other Act and any relevant Executive orders.

(C) Upon receipt of a report submitted under subparagraph (A), each House shall provide copies of the report to the chairman and ranking member of each standing committee with jurisdiction under the rules of the House of Representatives or the Senate to report a bill to amend the provision of law under which the rule is issued.

(2)(A) The Comptroller General shall provide a report on each major rule to the committees of jurisdiction in each House of the Congress by the end of 15 calendar days after the submission or publication date as provided in section 802(b)(2). The report of the Comptroller General shall include an assessment of the agency's compliance with procedural steps required by paragraph (1)(B).

(B) Federal agencies shall cooperate with the Comptroller General by providing information relevant to the Comptroller General's report under subparagraph (A).

(3) A major rule relating to a report submitted under paragraph (1) shall take effect on the latest of—

(A) the later of the date occurring 60 days after the date on which—

(i) the Congress receives the report submitted under paragraph (1); or

(ii) the rule is published in the Federal Register, if so published;

(B) if the Congress passes a joint resolution of disapproval described in section 802 relating to the rule, and the President signs a veto of such resolution, the earlier date—

(i) on which either House of Congress votes and fails to override the veto of the President; or

(ii) occurring 30 session days after the date on which the Congress received the veto and objections of the President; or

(C) the date the rule would have otherwise taken effect, if not for this section (unless a joint resolution of disapproval under section 802 is enacted).

(4) Except for a major rule, a rule shall take effect as otherwise provided by law after submission to Congress under paragraph (1).

(5) Notwithstanding paragraph (3), the effective date of a rule shall not be delayed by operation of this chapter beyond the date on which either House of Congress votes to reject a joint resolution of disapproval under section 802.

(b)(1) A rule shall not take effect (or continue), if the Congress enacts a joint resolution of disapproval, described under section 802, of the rule.

(2) A rule that does not take effect (or does not continue) under paragraph (1) may not be reissued in substantially the same form, and a new rule that is substantially the same as such a rule may not be issued, unless the reissued or new rule is specifically authorized by a law enacted after the date of the joint resolution disapproving the original rule.

(c)(1) Notwithstanding any other provision of this section (except subject to paragraph (3)), a

deliveries of insecticides and fungicides exempted by the Secretary.

SUBCHAPTER II—ENVIRONMENTAL PESTICIDE CONTROL

§§ 135 to 135k. Omitted

CODIFICATION

Sections 135 to 135k, acts June 25, 1947, ch. 125, §§2-13, 61 Stat. 163-172; Aug. 7, 1959, Pub. L. 86-139, §2, 73 Stat. 286; May 12, 1964, Pub. L. 88-305, §§1-6, 78 Stat. 190-193; Oct. 15, 1970, Pub. L. 91-452, title II, §204, 84 Stat. 928; Dec. 30, 1970, Pub. L. 91-601, §6(b), formerly §7(b), 84 Stat. 1673, renumbered, Aug. 13, 1981, Pub. L. 97-35, title XII, §1205(c), 95 Stat. 716, which related to economic poison control, were superseded by the amendments made to act June 25, 1947, by Pub. L. 92-516, Oct. 21, 1972, 86 Stat. 975. See section 4 of Pub. L. 92-516, set out as a note under section 136 of this title. The provisions of act June 25, 1947, as amended by Pub. L. 92-516, are set out in section 136 et seq. of this title.

Section 135 provided definitions for the purposes of this subchapter.

Section 135a related to prohibited acts.

Section 135b related to registration of economic poisons.

Section 135c related to access, inspection, and use in criminal prosecutions of books and records.

Section 135d related to rules and regulations, examination of economic poisons or devices, notification to violators, certification to United States attorney, duty of attorney, and publication of judgments.

Section 135e related to exemptions from penalties.

Section 135f provided for penalties.

Section 135g related to seizure, disposal, and award of costs against claimant.

Section 135h related to refusal of admission of imports.

Section 135i related to delegation of duties.

Section 135j related to authorization of appropriations and expenditure of funds.

Section 135k related to cooperation between departments and agencies.

§ 136. Definitions

For purposes of this subchapter—

(a) Active ingredient

The term “active ingredient” means—

(1) in the case of a pesticide other than a plant regulator, defoliant, desiccant, or nitrogen stabilizer, an ingredient which will prevent, destroy, repel, or mitigate any pest;

(2) in the case of a plant regulator, an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;

(3) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant;

(4) in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue; and

(5) in the case of a nitrogen stabilizer, an ingredient which will prevent or hinder the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria.

(b) Administrator

The term “Administrator” means the Administrator of the Environmental Protection Agency.

(c) Adulterated

The term “adulterated” applies to any pesticide if—

(1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;

(2) any substance has been substituted wholly or in part for the pesticide; or

(3) any valuable constituent of the pesticide has been wholly or in part abstracted.

(d) Animal

The term “animal” means all vertebrate and invertebrate species, including but not limited to man and other mammals, birds, fish, and shellfish.

(e) Certified applicator, etc.

(1) Certified applicator

The term “certified applicator” means any individual who is certified under section 136i of this title as authorized to use or supervise the use of any pesticide which is classified for restricted use. Any applicator who holds or applies registered pesticides, or uses dilutions of registered pesticides consistent with subsection (ee) of this section, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served is not deemed to be a seller or distributor of pesticides under this subchapter.

(2) Private applicator

The term “private applicator” means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by the applicator or the applicator’s employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

(3) Commercial applicator

The term “commercial applicator” means an applicator (whether or not the applicator is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by paragraph (2).

(4) Under the direct supervision of a certified applicator

Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.

(f) Defoliant

The term “defoliant” means any substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

(g) Desiccant

The term “desiccant” means any substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

(h) Device

The term “device” means any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.

(i) District court

The term “district court” means a United States district court, the District Court of Guam, the District Court of the Virgin Islands, and the highest court of American Samoa.

(j) Environment

The term “environment” includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these.

(k) Fungus

The term “fungus” means any non-chlorophyll-bearing thallophyte (that is, any non-chlorophyll-bearing plant of a lower order than mosses and liverworts), as for example, rust, smut, mildew, mold, yeast, and bacteria, except those on or in living man or other animals and those on or in processed food, beverages, or pharmaceuticals.

(l) Imminent hazard

The term “imminent hazard” means a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary pursuant to the Endangered Species Act of 1973 [16 U.S.C. 1531 et seq.].

(m) Inert ingredient

The term “inert ingredient” means an ingredient which is not active.

(n) Ingredient statement

The term “ingredient statement” means a statement which contains—

(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide; and

(2) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.

(o) Insect

The term “insect” means any of the numerous small invertebrate animals generally having the body more or less obviously segmented, for the most part belonging to the class insecta, comprising six-legged, usually winged forms, as for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and usually have more than six legs, as for example, spiders, mites, ticks, centipedes, and wood lice.

(p) Label and labeling**(1) Label**

The term “label” means the written, printed, or graphic matter on, or attached to, the

pesticide or device or any of its containers or wrappers.

(2) Labeling

The term “labeling” means all labels and all other written, printed, or graphic matter—

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) Misbranded

(1) A pesticide is misbranded if—

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: “Not Registered for Use in the United States of America”.

(2) A pesticide is misbranded if—

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if—

(i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—

(i) the name and address of the producer, registrant, or person for whom produced;

(ii) the name, brand, or trademark under which the pesticide is sold;

(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification; and

(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this subchapter—

(i) the skull and crossbones;

(ii) the word “poison” prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

(r) Nematode

The term “nematode” means invertebrate animals of the phylum nemathelminthes and class nematoda, that is, unsegmented round worms with elongated, fusiform, or saclike bodies covered with cuticle, and inhabiting soil, water, plants, or plant parts; may also be called nemas or eelworms.

(s) Person

The term “person” means any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.

(t) Pest

The term “pest” means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 136w(c)(1) of this title.

(u) Pesticide

The term “pesticide” means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer, except that the term “pesticide” shall not include any article that is a “new animal drug” within the meaning of section 321(w)¹ of title 21, that has been determined by the Secretary of Health and Human Services not to be a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed within the meaning of section 321(x)¹ of title 21 bearing or containing a new animal drug. The term “pesticide” does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 321 of title 21. For purposes of the preceding sentence, the term “critical device” includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term “semi-critical device” includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

(v) Plant regulator

The term “plant regulator” means any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term “plant regulator” shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

(w) Producer and produce

The term “producer” means the person who manufactures, prepares, compounds, propagates, or processes any pesticide or device or active ingredient used in producing a pesticide. The term “produce” means to manufacture, prepare, compound, propagate, or process any pesticide or device or active ingredient used in producing a

¹ See References in Text note below.

pesticide. The dilution by individuals of formulated pesticides for their own use and according to the directions on registered labels shall not of itself result in such individuals being included in the definition of “producer” for the purposes of this subchapter.

(x) Protect health and the environment

The terms “protect health and the environment” and “protection of health and the environment” mean protection against any unreasonable adverse effects on the environment.

(y) Registrant

The term “registrant” means a person who has registered any pesticide pursuant to the provisions of this subchapter.

(z) Registration

The term “registration” includes reregistration.

(aa) State

The term “State” means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa.

(bb) Unreasonable adverse effects on the environment

The term “unreasonable adverse effects on the environment” means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

(cc) Weed

The term “weed” means any plant which grows where not wanted.

(dd) Establishment

The term “establishment” means any place where a pesticide or device or active ingredient used in producing a pesticide is produced, or held, for distribution or sale.

(ee) To use any registered pesticide in a manner inconsistent with its labeling

The term “to use any registered pesticide in a manner inconsistent with its labeling” means to use any registered pesticide in a manner not permitted by the labeling, except that the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide

may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment, (3) employing any method of application not prohibited by the labeling unless the labeling specifically states that the product may be applied only by the methods specified on the labeling, (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling, (5) any use of a pesticide in conformance with section 136c, 136p, or 136v of this title, or (6) any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this subchapter. After March 31, 1979, the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.

(ff) Outstanding data requirement

(1) In general

The term “outstanding data requirement” means a requirement for any study, information, or data that is necessary to make a determination under section 136a(c)(5) of this title and which study, information, or data—

(A) has not been submitted to the Administrator; or

(B) if submitted to the Administrator, the Administrator has determined must be resubmitted because it is not valid, complete, or adequate to make a determination under section 136a(c)(5) of this title and the regulations and guidelines issued under such section.

(2) Factors

In making a determination under paragraph (1)(B) respecting a study, the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

(gg) To distribute or sell

The term “to distribute or sell” means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticides or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

(hh) Nitrogen stabilizer

The term “nitrogen stabilizer” means any substance or mixture of substances intended for preventing or hindering the process of nitrification, denitrification, ammonia volatilization, or urease production through action upon soil bacteria. Such term shall not include—

- (1) dicyandiamide;
- (2) ammonium thiosulfate; or
- (3) any substance or mixture of substances.—²
 - (A) that was not registered pursuant to section 136a of this title prior to January 1, 1992; and
 - (B) that was in commercial agronomic use prior to January 1, 1992, with respect to which after January 1, 1992, the distributor or seller of the substance or mixture has made no specific claim of prevention or hindering of the process of nitrification, denitrification, ammonia volatilization³ urease production regardless of the actual use or purpose for, or future use or purpose for, the substance or mixture.

Statements made in materials required to be submitted to any State legislative or regulatory authority, or required by such authority to be included in the labeling or other literature accompanying any such substance or mixture shall not be deemed a specific claim within the meaning of this subsection.

(jj) ⁴ Maintenance applicator

The term “maintenance applicator” means any individual who, in the principal course of such individual’s employment, uses, or supervises the use of, a pesticide not classified for restricted use (other than a ready to use consumer products pesticide); for the purpose of providing structural pest control or lawn pest control including janitors, general maintenance personnel, sanitation personnel, and grounds maintenance personnel. The term “maintenance applicator” does not include private applicators as defined in subsection (e)(2) of this section; individuals who use antimicrobial pesticides, sanitizers or disinfectants; individuals employed by Federal, State, and local governments or any political subdivisions thereof, or individuals who use pesticides not classified for restricted use in or around their homes, boats, sod farms, nurseries, greenhouses, or other noncommercial property.

(kk) Service technician

The term “service technician” means any individual who uses or supervises the use of pesticides (other than a ready to use consumer products pesticide) for the purpose of providing structural pest control or lawn pest control on the property of another for a fee. The term “service technician” does not include individuals who use antimicrobial pesticides, sanitizers or disinfectants; or who otherwise apply ready to use consumer products pesticides.

(ll) Minor use

The term “minor use” means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where—

- (1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or
- (2) the Administrator, in consultation with the Secretary of Agriculture, determines that,

based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and—

- (A) there are insufficient efficacious alternative registered pesticides available for the use;
- (B) the alternatives to the pesticide use pose greater risks to the environment or human health;
- (C) the minor use pesticide plays or will play a significant part in managing pest resistance; or
- (D) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The status as a minor use under this subsection shall continue as long as the Administrator has not determined that, based on existing data, such use may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such status.

(mm) Antimicrobial pesticide

(1) In general

The term “antimicrobial pesticide” means a pesticide that—

- (A) is intended to—
 - (i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or
 - (ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) in the intended use is exempt from, or otherwise not subject to, a tolerance under section 346a of title 21 or a food additive regulation under section 348 of title 21.

(2) Excluded products

The term “antimicrobial pesticide” does not include—

- (A) a wood preservative or antifouling paint product for which a claim of pesticidal activity other than or in addition to an activity described in paragraph (1) is made;
- (B) an agricultural fungicide product; or
- (C) an aquatic herbicide product.

(3) Included products

The term “antimicrobial pesticide” does include any other chemical sterilant product (other than liquid chemical sterilant products exempt under subsection (u) of this section), any other disinfectant product, any other industrial microbiocide product, and any other preservative product that is not excluded by paragraph (2).

(nn) Public health pesticide

The term “public health pesticide” means any minor use pesticide product registered for use and used predominantly in public health programs for vector control or for other recognized health protection uses, including the prevention or mitigation of viruses, bacteria, or other microorganisms (other than viruses, bacteria, or

² So in original. Period probably should not appear.

³ So in original. Probably should be followed by “, or”.

⁴ So in original. No subsec. (ii) was enacted.

other microorganisms on or in living man or other living animal) that pose a threat to public health.

(oo) Vector

The term “vector” means any organism capable of transmitting the causative agent of human disease or capable of producing human discomfort or injury, including mosquitoes, flies, fleas, cockroaches, or other insects and ticks, mites, or rats.

(June 25, 1947, ch. 125, § 2, as added Pub. L. 92-516, § 2, Oct. 21, 1972, 86 Stat. 975; amended Pub. L. 93-205, § 13(f), Dec. 28, 1973, 87 Stat. 903; Pub. L. 94-140, § 9, Nov. 28, 1975, 89 Stat. 754; Pub. L. 95-396, § 1, Sept. 30, 1978, 92 Stat. 819; Pub. L. 100-532, title I, § 101, title VI, § 601(a), title VIII, § 801(a), Oct. 25, 1988, 102 Stat. 2655, 2677, 2679; Pub. L. 102-237, title X, § 1006(a)(1), (2), (b)(3)(A), (B), Dec. 13, 1991, 105 Stat. 1894, 1895; Pub. L. 104-170, title I, §§ 105(a), 120, title II, §§ 210(a), 221, 230, title III, § 304, Aug. 3, 1996, 110 Stat. 1490, 1492, 1493, 1502, 1508, 1512.)

REFERENCES IN TEXT

The Endangered Species Act of 1973, referred to in subsec. (f), is Pub. L. 93-205, Dec. 28, 1973, 87 Stat. 884, as amended, which is classified generally to chapter 35 (§1531 et seq.) of Title 16, Conservation. For complete classification of this Act to the Code, see Short Title note set out under section 1531 of Title 16 and Tables.

Section 321 of title 21, referred to in subsec. (u), was subsequently amended, and subsecs. (w) and (x) of section 321 no longer define the terms “new animal drug” and “animal feed”, respectively. However, such terms are defined elsewhere in that section.

Section 27(b) of Federal Pesticide Act of 1978, referred to in subsec. (ee), is section 27(b) of Pub. L. 95-396, Sept. 30, 1978, 92 Stat. 841, which was formerly set out as a note under section 136w-4 of this title.

PRIOR PROVISIONS

A prior section 2 of act June 25, 1947, was classified to section 135 of this title prior to amendment of act June 25, 1947, by Pub. L. 92-516.

AMENDMENTS

1996—Subsec. (a)(1). Pub. L. 104-170, § 105(a)(1)(A), substituted “defoliant, desiccant, or nitrogen stabilizer” for “defoliant, or desiccant”.

Subsec. (a)(5). Pub. L. 104-170, § 105(a)(1)(B)–(D), added par. (5).

Subsec. (u). Pub. L. 104-170, §§ 105(a)(2), 221(1), struck out “and” before “(2)”, inserted “and (3) any nitrogen stabilizer,” after “desiccant,” and inserted at end “The term ‘pesticide’ does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 321 of title 21. For purposes of the preceding sentence, the term ‘critical device’ includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term ‘semi-critical device’ includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.”

Subsec. (bb). Pub. L. 104-170, § 304, which directed amendment of section 2(bb) by inserting “(1)” after “means” and adding cl. (2), without specifying the Act being amended, was executed to this subsection, which is section 2(bb) of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress.

Pub. L. 104-170, § 230(a), inserted at end “The Administrator shall consider the risks and benefits of public

health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.”

Subsec. (hh). Pub. L. 104-170, § 105(a)(3), added subsec. (hh).

Subsecs. (jj), (kk). Pub. L. 104-170, § 120, added subsecs. (jj) and (kk).

Subsec. (ll). Pub. L. 104-170, § 210(a), added subsec. (ll).

Subsec. (mm). Pub. L. 104-170, § 221(2), added subsec. (mm).

Subsecs. (nn), (oo). Pub. L. 104-170, § 230(b), added subsecs. (nn) and (oo).

1991—Subsec. (e)(1). Pub. L. 102-237, § 1006(a)(1), substituted “section 136i” for “section 136b” and “uses dilutions” for “use dilutions” and made technical amendment to reference to subsection (ee) of this section involving corresponding provision of original act.

Subsec. (e)(2). Pub. L. 102-237, § 1006(b)(3)(A), substituted “the applicator or the applicator’s” for “him or his”.

Subsec. (e)(3). Pub. L. 102-237, § 1006(b)(3)(B), substituted “the applicator” for “he”.

Subsec. (q)(2)(A)(i). Pub. L. 102-237, § 1006(a)(2), substituted “size or form” for “size of form”.

1988—Subsec. (c). Pub. L. 100-532, § 801(a)(1), substituted “if—” for “if:”.

Subsec. (p)(2)(B). Pub. L. 100-532, § 801(a)(2), substituted “Health and Human Services” for “Health, Education, and Welfare”.

Subsec. (q)(2)(A). Pub. L. 100-532, § 801(a)(3), substituted “if—” for “if:”.

Subsec. (q)(2)(C)(iii). Pub. L. 100-532, § 801(a)(4), substituted “, except that” for “: *Provided*, That”.

Subsec. (u). Pub. L. 100-532, § 801(a)(5), substituted “, except that” for “: *Provided*, That”, struck out “(1)(a)” after “include any article” and “or (b)” after “section 321(w) of title 21,” and substituted “Health and Human Services” for “Health, Education, and Welfare”, “or that is” for “or (2) that is”, and “a new animal drug” for “an article covered by clause (1) of this proviso”.

Subsec. (ee). Pub. L. 100-532, §§ 601(a)(1), 801(a)(6), substituted “, except that” for “: *Provided*, That”, inserted “unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency” and “unless the labeling specifically states that the product may be applied only by the methods specified on the labeling”, substituted “labeling, (4) mixing” for “labeling, or (4) mixing”, “, (5)” for “: *Provided further*, That the term also shall not include”, “or (6) any use” for “or any use”, and “, After” for “: *And provided further*, That after”.

Subsec. (ff). Pub. L. 100-532, § 101, added subsec. (ff).

Subsec. (gg). Pub. L. 100-532, § 601(a)(2), added subsec. (gg).

1978—Subsec. (e)(1). Pub. L. 95-396, § 1(1), inserted provision deeming an applicator not a seller or distributor of pesticides when providing a service of controlling pests.

Subsec. (e)(3). Pub. L. 95-396, § 1(2), substituted “an applicator” for “a certified applicator”.

Subsec. (q)(1)(H). Pub. L. 95-396, § 1(3), added subpar. (H).

Subsec. (w). Pub. L. 95-396, § 1(4), (5), amended definition of “producer” and “produce” to include reference to active ingredient used in producing a pesticide and inserted provision that an individual did not become a producer when there was dilution of a pesticide for personal use according to directions on registered labels.

Subsec. (dd). Pub. L. 95-396, § 1(6), inserted “or active ingredient used in producing a pesticide”.

Subsec. (ee). Pub. L. 95-396, § 1(7), added subsec. (ee).

1975—Subsec. (u). Pub. L. 94-140 inserted proviso which excluded from term “pesticide” any article designated as “new animal drug” and any article denominated as animal feed.

1973—Subsec. (l). Pub. L. 93-205 substituted “or threatened by the Secretary pursuant to the Endangered Species Act of 1973” for “by the Secretary of the Interior under Public Law 91-135”.

EFFECTIVE DATE OF 1988 AMENDMENT

Section 901 of Pub. L. 100-532 provided that: “Except as otherwise provided in this Act, the amendments made by this Act [see Short Title of 1988 Amendment note below] shall take effect on the expiration of 60 days after the date of enactment of this Act [Oct. 25, 1988].”

EFFECTIVE DATE OF 1973 AMENDMENT

Amendment by Pub. L. 93-205 effective Dec. 28, 1973, see section 16 of Pub. L. 93-205, set out as an Effective Date note under section 1531 of Title 16, Conservation.

EFFECTIVE DATE

Section 4 of Pub. L. 92-516, as amended by Pub. L. 94-140, § 4, Nov. 28, 1975, 89 Stat. 752; Pub. L. 95-396, § 28, Sept. 30, 1978, 92 Stat. 842, provided that:

“(a) Except as otherwise provided in the Federal Insecticide, Fungicide, and Rodenticide Act [this subchapter], as amended by this Act and as otherwise provided by this section, the amendments made by this Act [see Short Title note set out below] shall take effect at the close of the date of the enactment of this Act [Oct. 21, 1972], provided if regulations are necessary for the implementation of any provision that becomes effective on the date of enactment, such regulations shall be promulgated and shall become effective within 90 days from the date of enactment of this Act.

“(b) The provisions of the Federal Insecticide, Fungicide, and Rodenticide Act [this subchapter] and the regulations thereunder as such existed prior to the enactment of this Act shall remain in effect until superseded by the amendments made by this Act and regulations thereunder.

“(c)(1) Two years after the enactment of this Act the Administrator shall have promulgated regulations providing for the registration and classification of pesticides under the provisions of this Act and thereafter shall register all new applications under such provisions.

“(2) Any requirements that a pesticide be registered for use only by a certified applicator shall not be effective until five years from the date of enactment of this Act.

“(3) A period of five years from date of enactment shall be provided for certification of applicators.

“(A) One year after the enactment of this Act the Administrator shall have prescribed the standards for the certification of applicators.

“(B) Each State desiring to certify applicators shall submit a State plan to the Administrator for the purpose provided by section 4(b).

“(C) As promptly as possible but in no event more than one year after submission of a State plan, the Administrator shall approve the State plan or disapprove it and indicate the reasons for disapproval. Consideration of plans resubmitted by States shall be expedited.

“(4) One year after the enactment of this Act the Administrator shall have promulgated and shall make effective regulations relating to the registration of establishments, permits for experimental use, and the keeping of books and records under the provisions of this Act.

“(d) No person shall be subject to any criminal or civil penalty imposed by the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by this Act, for any act (or failure to act) occurring before the expiration of 60 days after the Administrator has published effective regulations in the Federal Register and taken such other action as may be necessary to permit compliance with the provisions under which the penalty is to be imposed.

“(e) For purposes of determining any criminal or civil penalty or liability to any third person in respect

of any act or omission occurring before the expiration of the periods referred to in this section, the Federal Insecticide, Fungicide, and Rodenticide Act shall be treated as continuing in effect as if this Act had not been enacted.”

SHORT TITLE OF 2007 AMENDMENT

Pub. L. 110-94, § 1, Oct. 9, 2007, 121 Stat. 1000, provided that: “This Act [amending sections 136a, 136a-1, and 136w-8 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as a note under section 136a of this title] may be cited as the ‘Pesticide Registration Improvement Renewal Act’.”

SHORT TITLE OF 2004 AMENDMENT

Pub. L. 108-199, div. G, title V, § 501(a), Jan. 23, 2004, 118 Stat. 419, provided that: “This section [enacting section 136w-8 of this title, amending sections 136a, 136a-1, 136x, and 136y of this title, and enacting provisions set out as notes under section 136a of this title and section 346a of Title 21, Food and Drugs] may be cited as the ‘Pesticide Registration Improvement Act of 2003’.”

SHORT TITLE OF 1996 AMENDMENT

Section 1 of Pub. L. 104-170 provided that: “This Act [enacting sections 136i-2, 136r-1, and 136w-5 to 136w-7 of this title, amending this section, sections 136a, 136a-1, 136d, 136q, 136s, 136w, 136w-3, 136x, and 136y of this title, and sections 321, 331, 333, 342, and 346a of Title 21, Food and Drugs, and enacting provisions set out as notes under section 136i-2 of this title and sections 301 and 346a of Title 21] may be cited as the ‘Food Quality Protection Act of 1996’.”

[Another Food Quality Protection Act of 1996 was enacted by Pub. L. 104-170, title IV, 110 Stat. 1513, see section 401(a) of Pub. L. 104-170, set out as a note under section 301 of Title 21, Food and Drugs.]

SHORT TITLE OF 1988 AMENDMENT

Section 1(a) of Pub. L. 100-532 provided that: “This Act [enacting section 136a-1 of this title, amending this section and sections 136a to 136d, 136f to 136q, 136s, 136v to 136w-2, and 136y of this title, and enacting provisions set out as notes under this section and sections 136m and 136y of this title] may be cited as the ‘Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988’.”

SHORT TITLE OF 1978 AMENDMENT

Section 29 of Pub. L. 95-396 provided that: “This Act [enacting sections 136w-1 to 136w-4 of this title, amending this section and sections 136a to 136f, 136h, 136j, 136l, 136o, 136q, 136r, 136u to 136w, 136x, and 136y of this title, enacting provisions set out as notes under sections 136a, 136o, and 136w-4 of this title, and amending provisions set out as a note under this section] may be cited as the ‘Federal Pesticide Act of 1978’.”

SHORT TITLE

Section 1 of Pub. L. 92-516 provided: “That this Act [amending this subchapter generally, enacting notes set out under this section, and amending sections 1261 and 1471 of Title 15, Commerce and Trade, and sections 321 and 346a of Title 21, Foods and Drugs] may be cited as the ‘Federal Environmental Pesticide Control Act of 1972’.”

Section 1(a) of act June 25, 1947, as added by Pub. L. 92-516, § 2, provided that: “This Act [enacting this subchapter] may be cited as the ‘Federal Insecticide, Fungicide, and Rodenticide Act’.”

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

FEDERAL COMPLIANCE WITH POLLUTION CONTROL
STANDARDS

For provisions relating to the responsibility of the head of each Executive agency for compliance with applicable pollution control standards, see Ex. Ord. No. 12088, Oct. 13, 1978, 43 F.R. 47707, set out as a note under section 4321 of Title 42, The Public Health and Welfare.

§ 136a. Registration of pesticides**(a) Requirement of registration**

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

(b) Exemptions

A pesticide which is not registered with the Administrator may be transferred if—

(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

(c) Procedure for registration**(1) Statement required**

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the writ-

ten permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.

(ii) The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after August 3, 1996, and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that—

(I) there are insufficient efficacious alternative registered pesticides available for the use;

(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;

(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

(iii) Except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for re-registration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data

FEDERAL COMPLIANCE WITH POLLUTION CONTROL STANDARDS

For provisions relating to the responsibility of the head of each Executive agency for compliance with applicable pollution control standards, see Ex. Ord. No. 12088, Oct. 13, 1978, 43 F.R. 47707, set out as a note under section 4321 of Title 42, The Public Health and Welfare.

§ 136a. Registration of pesticides

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

(b) Exemptions

A pesticide which is not registered with the Administrator may be transferred if—

(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

(c) Procedure for registration

(1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the writ-

ten permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.

(ii) The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after August 3, 1996, and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that—

(I) there are insufficient efficacious alternative registered pesticides available for the use;

(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;

(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

(iii) Except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for re-registration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data

submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this subchapter, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation.

(iv) After expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under clauses (i), (ii), and (iii), the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.

(v) The period of exclusive use provided under clause (ii) shall not take effect until 1 year after August 3, 1996, except where an applicant or registrant is applying for the registration of a pesticide containing an active ingredient not previously registered.

(vi) With respect to data submitted after August 3, 1996, by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. The applicant or registrant at the time the new minor use is requested shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are subsequently used to support a nonminor use, the data shall no longer be subject to the exclusive use provisions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.

(G) If the applicant is requesting that the registration or amendment to the registration of a pesticide be expedited, an explanation of the basis for the request must be submitted, in accordance with paragraph (10) of this subsection.

(2) Data in support of registration

(A) In general

The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter the Administrator requires any additional kind of information under subparagraph (B) of this paragraph, the Administrator shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, the pub-

lic health and agricultural need for such minor use, and the level and degree of potential beneficial or adverse effects on man and the environment. The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this subchapter, any field residue data from a geographic area where the pesticide will not be registered for such use. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 136h of this title, within 30 days after the Administrator registers a pesticide under this subchapter the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision.

(B) Additional data

(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and deter-

mination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iv) Notwithstanding any other provision of this subchapter, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this subchapter, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of

paragraph (1)(D). Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

(vi) Upon the request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under section 136a-1 of this title for the other uses of the pesticide established as of August 3, 1996, if—

(I) the data to support other uses of the pesticide on a food are being provided;

(II) the registrant, in submitting a request for such an extension, provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(III) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under section 136a-1 of this title; and

(IV) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date established by the Administrator for the submission of the data.

(vii) If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written

request of the registrant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under section 136a-1 of this title for the supported uses identified pursuant to this clause unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding the provisions of this clause, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(viii)(I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.

(II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).

(III) Not later than 1 year after August 3, 1996, the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.

(C) Simplified procedures

Within nine months after September 30, 1978, the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

(D) Exemption

No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to—

- (i) submit or cite data pertaining to such purchased product; or
- (ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

(E) Minor use waiver

In handling the registration of a pesticide for a minor use, the Administrator may waive otherwise applicable data requirements if the Administrator determines that the absence of such data will not prevent the Administrator from determining—

- (i) the incremental risk presented by the minor use of the pesticide; and
- (ii) that such risk, if any, would not be an unreasonable adverse effect on the environment.

(3) Application**(A) In general**

The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of the Administrator's determination that it does not comply with the provisions of the subchapter in accordance with paragraph (6).

(B) Identical or substantially similar

(i) The Administrator shall, as expeditiously as possible, review and act on any application received by the Administrator that—

- (I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or
- (II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.

(ii) In expediting the review of an application for an action described in clause (i), the Administrator shall—

- (I) review the application in accordance with section 136w-8(f)(4)(B) of this title and, if the application is found to be incomplete, reject the application;
- (II) not later than the applicable decision review time established pursuant to section 136w-8(f)(4)(B) of this title, or, if no review time is established, not later than 90 days after receiving a complete application, notify the registrant if the application has been granted or denied; and

(III) if the application is denied, notify the registrant in writing of the specific reasons for the denial of the application.

(C) Minor use registration

(i) The Administrator shall, as expeditiously as possible, review and act on any complete application—

- (I) that proposes the initial registration of a new pesticide active ingredient if the active ingredient is proposed to be registered solely for minor uses, or proposes a registration amendment solely for minor uses to an existing registration; or
- (II) for a registration or a registration amendment that proposes significant minor uses.

(ii) For the purposes of clause (i)—

- (I) the term “as expeditiously as possible” means that the Administrator shall, to the greatest extent practicable, complete a review and evaluation of all data, submitted with a complete application, within 12 months after the submission of the complete application, and the failure of the Administrator to complete such a review and evaluation under clause (i) shall not be subject to judicial review; and
- (II) the term “significant minor uses” means 3 or more minor uses proposed for every nonminor use, a minor use that would, in the judgment of the Administrator, serve as a replacement for any use which has been canceled in the 5 years preceding the receipt of the application, or a minor use that in the opinion of the Administrator would avoid the reissuance of an emergency exemption under section 136p of this title for that minor use.

(D) Adequate time for submission of minor use data

If a registrant makes a request for a minor use waiver, regarding data required by the Administrator, pursuant to paragraph (2)(E), and if the Administrator denies in whole or in part such data waiver request, the registrant shall have a full-time period for providing such data. For purposes of this subparagraph, the term “full-time period” means the time period originally established by the Administrator for submission of such data, beginning with the date of receipt by the registrant of the Administrator's notice of denial.

(4) Notice of application

The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

(5) Approval of registration

The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d) of this section—

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

(6) Denial of registration

If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant for registration of the Administrator's determination and of the Administrator's reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the Administrator's decision and of the Administrator's reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 136d of this title.

(7) Registration under special circumstances

Notwithstanding the provisions of paragraph (5)—

(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any un-

reasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this subchapter, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such pe-

riod the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on such other conditions as the Administrator may prescribe. A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

(8) Interim administrative review

Notwithstanding any other provision of this subchapter, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this subchapter, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms “validated test” and “other significant evidence” as used herein shall be published by the Administrator in the Federal Register.

(9) Labeling

(A) Additional statements

Subject to subparagraphs (B) and (C), it shall not be a violation of this subchapter for a registrant to modify the labeling of an antimicrobial pesticide product to include relevant information on product efficacy, product composition, container composition or design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity.

(B) Requirements

Proposed labeling information under subparagraph (A) shall not be false or misleading, shall not conflict with or detract from any statement required by law or the Administrator as a condition of registration, and shall be substantiated on the request of the Administrator.

(C) Notification and disapproval

(i) Notification

A registration may be modified under subparagraph (A) if—

- (I) the registrant notifies the Administrator in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling; and
- (II) the Administrator does not disapprove of the modification under clause (ii).

(ii) Disapproval

Not later than 30 days after receipt of a notification under clause (i), the Administrator may disapprove the modification by sending the registrant notification in writing stating that the proposed language is not acceptable and stating the reasons why the Administrator finds the proposed modification unacceptable.

(iii) Restriction on sale

A registrant may not sell or distribute a product bearing a disapproved modification.

(iv) Objection

A registrant may file an objection in writing to a disapproval under clause (ii) not later than 30 days after receipt of notification of the disapproval.

(v) Final action

A decision by the Administrator following receipt and consideration of an objection filed under clause (iv) shall be considered a final agency action.

(D) Use dilution

The label or labeling required under this subchapter for an antimicrobial pesticide that is or may be diluted for use may have a different statement of caution or protective measures for use of the recommended diluted solution of the pesticide than for use of a concentrate of the pesticide if the Administrator determines that—

- (i) adequate data have been submitted to support the statement proposed for the diluted solution uses; and
- (ii) the label or labeling provides adequate protection for exposure to the diluted solution of the pesticide.

(10) Expedited registration of pesticides

(A) Not later than 1 year after August 3, 1996, the Administrator shall, utilizing public comment, develop procedures and guidelines, and expedite the review of an application for registration of a pesticide or an amendment to a registration that satisfies such guidelines.

(B) Any application for registration or an amendment, including biological and conventional pesticides, will be considered for expedited review under this paragraph. An application for registration or an amendment shall qualify for expedited review if use of the pesticide proposed by the application may reasonably be expected to accomplish 1 or more of the following:

- (i) Reduce the risks of pesticides to human health.
- (ii) Reduce the risks of pesticides to non-target organisms.
- (iii) Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources.
- (iv) Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective.

(C) The Administrator, not later than 30 days after receipt of an application for expedited review, shall notify the applicant whether the application is complete. If it is found to be incomplete, the Administrator may either reject the request for expedited review or ask the applicant for additional information to satisfy the guidelines developed under subparagraph (A).

(d) Classification of pesticides

(1) Classification for general use, restricted use, or both

(A) As a part of the registration of a pesticide the Administrator shall classify it as

being for general use or for restricted use. If the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, the Administrator shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation on the initial classification, and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use, and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses. The Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.

(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, the Administrator will classify the pesticide, or the particular use or uses of the pesticide to which the determination applies, for general use.

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, the Administrator shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:

(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

(2) Change in classification

If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, the Administrator shall notify the registrant of such pesticide of such determination at least forty-five days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under section 136d(b) of this title.

(3) Change in classification from restricted use to general use

The registrant of any pesticide with one or more uses classified for restricted use may petition the Administrator to change any such classification from restricted to general use. Such petition shall set out the basis for the registrant's position that restricted use classification is unnecessary because classification of the pesticide for general use would not cause unreasonable adverse effects on the environment. The Administrator, within sixty days after receiving such petition, shall notify the registrant whether the petition has been granted or denied. Any denial shall contain an explanation therefor and any such denial shall be subject to judicial review under section 136n of this title.

(e) Products with same formulation and claims

Products which have the same formulation, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same pesticide may be registered as a single pesticide; and additional names and labels shall be added to the registration by supplemental statements.

(f) Miscellaneous

(1) Effect of change of labeling or formulation

If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this subchapter.

(2) Registration not a defense

In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.

(3) Authority to consult other Federal agencies

In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

(4) Mixtures of nitrogen stabilizers and fertilizer products

Any mixture or other combination of—

(A) 1 or more nitrogen stabilizers registered under this subchapter; and

(B) 1 or more fertilizer products,

shall not be subject to the provisions of this section or sections 136a-1, 136c, 136e, 136m, and 136o(a)(2) of this title if the mixture or other combination is accompanied by the labeling required under this subchapter for the nitrogen stabilizer contained in the mixture or other combination, the mixture or combination is mixed or combined in accordance with such labeling, and the mixture or combination does not contain any active ingredient other than the nitrogen stabilizer.

(g) Registration review

(1) General rule

(A) Periodic review

(i) In general

The registrations of pesticides are to be periodically reviewed.

(ii) Regulations

In accordance with this subparagraph, the Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations.

(iii) Initial registration review

The Administrator shall complete the registration review of each pesticide or pesticide case, which may be composed of 1 or more active ingredients and the products associated with the active ingredients, not later than the later of—

(I) October 1, 2022; or

(II) the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered.

(iv) Subsequent registration review

Not later than 15 years after the date on which the initial registration review is completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subsequent registration review for each pesticide or pesticide case.

(v) Cancellation

No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 136d of this title.

(B) Docketing

(i) In general

Subject to clause (ii), after meeting with 1 or more individuals that are not government employees to discuss matters relating to a registration review, the Administrator shall place in the docket minutes of the meeting, a list of attendees, and any documents exchanged at the meeting, not later than the earlier of—

(I) the date that is 45 days after the meeting; or

(II) the date of issuance of the registration review decision.

(ii) Protected information

The Administrator shall identify, but not include in the docket, any confidential business information the disclosure of

which is prohibited by section 136h of this title.

(C) Limitation

Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide pursuant to this subchapter.

(2) Data

(A) Submission required

The Administrator shall use the authority in subsection (c)(2)(B) of this section to require the submission of data when such data are necessary for a registration review.

(B) Data submission, compensation, and exemption

For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) of this section shall be utilized for and be applicable to any data required for registration review.

(h) Registration requirements for antimicrobial pesticides

(1) Evaluation of process

To the maximum extent practicable consistent with the degrees of risk presented by an antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of August 3, 1996, for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products, including—

(A) new antimicrobial active ingredients;

(B) new antimicrobial end-use products;

(C) substantially similar or identical antimicrobial pesticides; and

(D) amendments to antimicrobial pesticide registrations.

(2) Review time period reduction goal

Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk, to a period of not more than—

(A) 540 days for a new antimicrobial active ingredient pesticide registration;

(B) 270 days for a new antimicrobial use of a registered active ingredient;

(C) 120 days for any other new antimicrobial product;

(D) 90 days for a substantially similar or identical antimicrobial product;

(E) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(F) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this paragraph.

(3) Implementation

(A) Proposed rulemaking

(i) Issuance

Not later than 270 days after August 3, 1996, the Administrator shall publish in

the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

(ii) Requirements

Proposed regulations issued under clause (i) shall—

(I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, and pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;

(II) differentiate the types of review undertaken for antimicrobial pesticides;

(III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this subchapter, considering the use patterns of the product, toxicity, expected exposure, and product type;

(IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made; and

(V) implement effective and reliable deadlines for process management.

(iii) Comments

In developing the proposed regulations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

(B) Final regulations

(i) Issuance

The Administrator shall issue final regulations not later than 240 days after the close of the comment period for the proposed regulations.

(ii) Failure to meet goal

If a goal described in paragraph (2) is not met by the final regulations, the Administrator shall identify the goal, explain why the goal was not attained, describe the element of the regulations included instead, and identify future steps to attain the goal.

(iii) Requirements

In issuing final regulations, the Administrator shall—

(I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly

managed, consistent with the degree of risk, in the most cost-efficient manner;

(II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process;

(III) use all appropriate and cost-effective review mechanisms, including—

(aa) expanded use of notification and non-notification procedures;

(bb) revised procedures for application review; and

(cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and

(IV) clarify criteria for determination of the completeness of an application.

(C) Expedited review

This subsection does not affect the requirements or extend the deadlines or review periods contained in subsection (c)(3) of this section.

(D) Alternative review periods

If the final regulations to carry out this paragraph are not effective 630 days after August 3, 1996, until the final regulations become effective, the review period, beginning on the date of receipt by the Agency of a complete application, shall be—

(i) 2 years for a new antimicrobial active ingredient pesticide registration;

(ii) 1 year for a new antimicrobial use of a registered active ingredient;

(iii) 180 days for any other new antimicrobial product;

(iv) 90 days for a substantially similar or identical antimicrobial product;

(v) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(vi) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this subparagraph.

(E) Wood preservatives

An application for the registration, or for an amendment to the registration, of a wood preservative product for which a claim of pesticidal activity listed in section 136(mm) of this title is made (regardless of any other pesticidal claim that is made with respect to the product) shall be reviewed by the Administrator within the same period as that established under this paragraph for an antimicrobial pesticide product application, consistent with the degree of risk posed by the use of the wood preservative product, if the application requires the applicant to satisfy the same data requirements as are required to support an application for a wood preservative product that is an antimicrobial pesticide.

(F) Notification

(i) In general

Subject to clause (iii), the Administrator shall notify an applicant whether an application has been granted or denied not later

than the final day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

(ii) Final decision

If the Administrator fails to notify an applicant within the period of time required under clause (i), the failure shall be considered an agency action unlawfully withheld or unreasonably delayed for purposes of judicial review under chapter 7 of title 5.

(iii) Exemption

This subparagraph does not apply to an application for an antimicrobial pesticide that is filed under subsection (c)(3)(B) of this section prior to 90 days after August 3, 1996.

(iv) Limitation

Notwithstanding clause (ii), the failure of the Administrator to notify an applicant for an amendment to a registration for an antimicrobial pesticide shall not be judicially reviewable in a Federal or State court if the amendment requires scientific review of data within—

(I) the time period specified in subparagraph (D)(vi), in the absence of a final regulation under subparagraph (B); or

(II) the time period specified in paragraph (2)(F), if adopted in a final regulation under subparagraph (B).

(4) Annual report

(A) Submission

Beginning on August 3, 1996, and ending on the date that the goals under paragraph (2) are achieved, the Administrator shall, not later than March 1 of each year, prepare and submit an annual report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(B) Requirements

A report submitted under subparagraph (A) shall include a description of—

(i) measures taken to reduce the backlog of pending registration applications;

(ii) progress toward achieving reforms under this subsection; and

(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.

(June 25, 1947, ch. 125, § 3, as added Pub. L. 92-516, § 2, Oct. 21, 1972, 86 Stat. 979; amended Pub. L. 94-140, § 12, Nov. 28, 1975, 89 Stat. 755; Pub. L. 95-396, §§ 2(a), 3-8, Sept. 30, 1978, 92 Stat. 820, 824-827; Pub. L. 100-532, title I, §§ 102(b), 103, title VI, § 601(b)(1), title VIII, § 801(b), Oct. 25, 1988, 102 Stat. 2667, 2677, 2680; Pub. L. 101-624, title XIV, § 1492, Nov. 28, 1990, 104 Stat. 3628; Pub. L. 102-237, title X, § 1006(a)(3), (b)(1), (2), (c), Dec. 13, 1991, 105 Stat. 1894-1896; Pub. L. 104-170, title I, §§ 105(b), 106(b), title II, §§ 210(b), (c)(1), (d), (e), (f)(2), 222-224, 231, 250, Aug. 3, 1996, 110 Stat. 1491, 1494-1497, 1499, 1503, 1504, 1508, 1510; Pub. L. 108-199, div. G, title V, § 501(b), Jan. 23, 2004, 118

Stat. 419; Pub. L. 110-94, §§ 2, 3, Oct. 9, 2007, 121 Stat. 1000.)

PRIOR PROVISIONS

A prior section 3 of act June 25, 1947, was classified to section 135a of this title prior to amendment of act June 25, 1947, by Pub. L. 92-516.

AMENDMENTS

2007—Subsec. (c)(3)(B)(ii)(I). Pub. L. 110-94, § 2(1), substituted “review the application in accordance with section 136w-8(f)(4)(B) of this title and,” for “within 45 days after receiving the application, notify the registrant whether or not the application is complete and,”.

Subsec. (c)(3)(B)(ii)(II). Pub. L. 110-94, § 2(2), substituted “not later than the applicable decision review time established pursuant to section 136w-8(f)(4)(B) of this title, or, if no review time is established, not later than” for “within”.

Subsec. (g)(1)(A). Pub. L. 110-94, § 3(1), designated first sentence as cl. (i) and inserted heading, designated second sentence as cl. (ii), inserted heading, and substituted “In accordance with this subparagraph, the Administrator” for “The Administrator”, added cls. (iii) and (iv), designated fourth sentence as cl. (v) and inserted heading, and struck out third sentence which read as follows: “The goal of these regulations shall be a review of a pesticide’s registration every 15 years.”

Subsec. (g)(1)(B), (C). Pub. L. 110-94, § 3(2), (3), added subpar. (B) and redesignated former subpar. (B) as (C).

2004—Subsec. (h)(2)(F). Pub. L. 108-199, § 501(b)(1), substituted “120 days” for “90 to 180 days”.

Subsec. (h)(3)(D)(vi). Pub. L. 108-199, § 501(b)(2)(A), substituted “120 days” for “240 days”.

Subsec. (h)(3)(F)(iv). Pub. L. 108-199, § 501(b)(2)(B), added cl. (iv).

1996—Subsec. (c)(1)(F)(ii) to (vi). Pub. L. 104-170, § 210(b), added cls. (ii), (v), and (vi), redesignated former cls. (ii) and (iii) as (iii) and (iv), respectively, and in cl. (iv) substituted “(i), (ii), and (iii)” for “(i) and (ii)”.

Subsec. (c)(1)(G). Pub. L. 104-170, § 250(1), added subpar. (G).

Subsec. (c)(2)(A). Pub. L. 104-170, §§ 210(d)(1), 231, inserted heading, inserted “the public health and agricultural need for such minor use,” after “pattern of use,” and substituted “potential beneficial or adverse effects on man and the environment” for “potential exposure of man and the environment to the pesticide”.

Subsec. (c)(2)(B). Pub. L. 104-170, § 210(d)(2), inserted heading.

Subsec. (c)(2)(B)(vi). Pub. L. 104-170, § 210(c)(1), added cl. (vi).

Subsec. (c)(2)(B)(vii). Pub. L. 104-170, § 210(f)(2), added cl. (vii).

Subsec. (c)(2)(B)(viii). Pub. L. 104-170, § 222, added cl. (viii).

Subsec. (c)(2)(C). Pub. L. 104-170, § 210(d)(3), inserted heading.

Subsec. (c)(2)(E). Pub. L. 104-170, § 210(d)(4), added subpar. (E).

Subsec. (c)(3)(A), (B). Pub. L. 104-170, § 210(e)(1), (2), inserted headings.

Subsec. (c)(3)(C), (D). Pub. L. 104-170, § 210(e)(3), added subpars. (C) and (D).

Subsec. (c)(9). Pub. L. 104-170, § 223, added par. (9).

Subsec. (c)(10). Pub. L. 104-170, § 250(2), added par. (10).

Subsec. (f)(4). Pub. L. 104-170, § 105(b), added par. (4).

Subsec. (g). Pub. L. 104-170, § 106(b), added subsec. (g).

Subsec. (h). Pub. L. 104-170, § 224, added subsec. (h).

1991—Subsec. (c)(1)(D). Pub. L. 102-237, § 1006(a)(3)(B), (C), added subpar. (D) and redesignated former subpar. (D) as (F’).

Subsec. (c)(1)(E). Pub. L. 102-237, § 1006(a)(3)(A), (C), added subpar. (E) and struck out former subpar. (E) which read as follows: “the complete formula of the pesticide; and”.

Subsec. (c)(1)(F). Pub. L. 102-237, § 1006(a)(3)(A), (B), (D), redesignated former subpar. (D) as (F’), in cl. (i)

substituted “With” for “with” and a period for semicolon at end, in cl. (ii) substituted “Except” for “except” and a period for semicolon at end, in cl. (iii) substituted “After” for “after” and a period for semicolon at end, and struck out former subpar. (F) which read as follows: “a request that the pesticide be classified for general use, for restricted use, or for both.”

Subsec. (c)(2)(A). Pub. L. 102-237, §1006(b)(1), (2), substituted “the Administrator” for “he” before “requires”, “shall permit”, “shall make”, and “deems”, and substituted “the Administrator’s” for “his”.

Subsec. (c)(2)(D). Pub. L. 102-237, §1006(c), clarified amendment made by Pub. L. 100-532, §102(b)(2)(A). See 1988 Amendment note below.

Subsec. (c)(3)(A). Pub. L. 102-237, §1006(b)(2), substituted “the Administrator’s” for “his”.

Subsec. (c)(5). Pub. L. 102-237, §1006(b)(1), substituted “the Administrator” for “he” before “determines”.

Subsec. (c)(6). Pub. L. 102-237, §1006(b)(1), (2), substituted “the Administrator” for “he” before “shall notify” in two places and “the Administrator’s” for “his” in four places.

Subsec. (d)(1). Pub. L. 102-237, §1006(b)(1), substituted “the Administrator” for “he” before “shall classify it for both” in subpar. (A), before “will classify” in subpar. (B), and before “shall classify” in subpar. (C).

Subsec. (d)(2). Pub. L. 102-237, §1006(b)(1), substituted “the Administrator” for “he” before “shall notify”.

1990—Subsec. (c)(2)(A). Pub. L. 101-624 inserted after third sentence “The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this subchapter, any field residue data from a geographic area where the pesticide will not be registered for such use.”

1988—Subsec. (a). Pub. L. 100-532, §601(b)(1), substituted “Requirement of registration” for “Requirement” in heading and amended text generally. Prior to amendment, text read as follows: “Except as otherwise provided by this subchapter, no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator.”

Subsec. (c)(1)(D). Pub. L. 100-532, §801(b)(1)–(4), in introductory provisions, substituted “paragraph (2)(D)” for “subsection (c)(2)(D) of this section”, in cl. (i), substituted “(i) with” for “(i) With” and “, except that” for “: *Provided*, That”, in cl. (ii), substituted “clause (i)” for “subparagraph (D)(i) of this paragraph”, and in cl. (iii), substituted “clauses (i) and (ii)” for “subparagraphs (D)(i) and (D)(ii) of this paragraph”.

Subsec. (c)(2)(A). Pub. L. 100-532, §801(b)(5)(A), (B), substituted “(2) Data in support of registration.—”

“(A) The” for “(2)(A) Data in support of registration.—The”, and directed that subpar. (A) be aligned with left margin of subsec. (d)(1)(A) of this section.

Subsec. (c)(2)(B). Pub. L. 100-532, §§102(b)(1), 801(b)(5)(C)–(F), substituted “(B)(i) If” for “(B) Additional data to support existing registration.—(i) If”, directed that cls. (ii) to (v) be aligned with left margin of subpar. (A), in cls. (ii) and (iii), inserted “The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.”, in cl. (iv), substituted “title. The only” for “title: *Provided*, that the only”, and in cl. (v), substituted “paragraph (1)(D)” for “subsection (c)(1)(D) of this section”.

Subsec. (c)(2)(C). Pub. L. 100-532, §801(b)(5)(G), (H), struck out “Simplified procedures” after “(C)” and directed that text be aligned with left margin of subpar. (A).

Subsec. (c)(2)(D). Pub. L. 100-532, §102(b)(2)(A), and Pub. L. 102-237, §1006(c), substituted “the pesticide that is the subject of the application” for “an end-use product”.

Subsec. (c)(2)(D)(i). Pub. L. 100-532, §102(b)(2)(B), struck out “the safety of” after “data pertaining to”.

Subsec. (c)(3). Pub. L. 100-532, §103, substituted “(A) The Administrator” for “The Administrator” and added subpar. (B).

Subsec. (c)(7). Pub. L. 100-532, §801(b)(6), in introductory provisions, substituted “paragraph (5)” for “subsection (c)(5) of this section”, in subpars. (A) and (B), substituted “paragraph (5). If” for “subsection (c)(5) of this section: *Provided*, That, if”, and in subpar. (C), substituted “prescribe. A” for “prescribe: *Provided*, that a”.

Subsec. (d)(1)(A). Pub. L. 100-532, §801(b)(7), substituted “restricted use. If” for “restricted use, provided that if” and “restricted uses. The Administrator” for “restricted uses: *Provided*, however, That the Administrator”.

Subsec. (f)(2). Pub. L. 100-532, §801(b)(8), substituted “this subchapter. As” for “this subchapter: *Provided*, That as”.

Subsec. (g). Pub. L. 100-532, §801(b)(9), struck out subsec. (g) which read as follows: “The Administrator shall accomplish the reregistration of all pesticides in the most expeditious manner practicable: *Provided*, That, to the extent appropriate, any pesticide that results in a postharvest residue in or on food or feed crops shall be given priority in the reregistration process.”

1978—Subsec. (c)(1)(D). Pub. L. 95-396, §2(a)(1), added subpar. (D), and struck out provisions which required the applicant for registration of a pesticide to file with the Administrator a statement containing “if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, except that data submitted on or after January 1, 1970, in support of an application shall not, without permission of the applicant, be considered by the Administrator in support of any other application for registration unless such other applicant shall have first offered to pay reasonable compensation for producing the test data to be relied upon and such data is not protected from disclosure by section 136h(b) of this title. This provision with regard to compensation for producing the test data to be relied upon shall apply with respect to all applications for registration or reregistration submitted on or after October 21, 1972. If the parties cannot agree on the amount and method of payment, the Administrator shall make such determination and may fix such other terms and conditions as may be reasonable under the circumstances. The Administrator’s determination shall be made on the record after notice and opportunity for hearing. If either party does not agree with said determination, he may, within thirty days, take an appeal to the Federal district court for the district in which he resides with respect to either the amount of the payment or the terms of payment, or both. Registration shall not be delayed pending the determination of reasonable compensation between the applicants, by the Administrator or by the court.”

Subsec. (c)(2). Pub. L. 95-396, §§2(a)(2)(A)–(D), 3, 4, designated existing provisions as subpar. (A), inserted in second sentence “under subparagraph (B) of this paragraph” after “kind of information”, struck out from introductory text of third sentence “subsection (c)(1)(D) of this section and” after “Except as provided by”, and inserted provisions relating to establishment of standards for data requirements for registration of pesticides with respect to minor uses and consideration of economic factors in development of standards and cost of development, and added subpars. (B) to (D).

Subsec. (c)(5). Pub. L. 95-396, §5, provided for waiver of data requirements pertaining to efficacy.

Subsec. (c)(7), (8). Pub. L. 95-396, §6, added pars. (7) and (8).

Subsec. (d)(1)(A). Pub. L. 95-396, §7(1), authorized classification of pesticide uses by regulation on the initial classification and registered pesticides prior to reregistration.

Subsec. (d)(2). Pub. L. 95-396, §7(2), substituted “forty-five days” for “30 days”.

Subsec. (d)(3). Pub. L. 95-396, §7(3), added par. (3).

Subsec. (g). Pub. L. 95-396, §8, added subsec. (g).

1975—Subsec. (c)(1)(D). Pub. L. 94-140 inserted exception relating to test data submitted on or after January 1, 1970, in support of application, inserted provision that compensation for producing test data shall apply to all applications submitted on or after October 21, 1972, and provision relating to delay of registration pending determination of reasonable compensation, struck out requirement that payment determined by court not be less than amount determined by Administrator, and substituted “If either party” for “If the owner of the test data”.

EFFECTIVE DATE OF 2007 AMENDMENT

Pub. L. 110-94, § 6, Oct. 9, 2007, 121 Stat. 1007, provided that: “This Act [see Short Title of 2007 Amendment note set out under section 136 of this title] and the amendments made by this Act take effect on October 1, 2007.”

EFFECTIVE DATE OF 2004 AMENDMENT

Pub. L. 108-199, div. G, title V, § 501(h), Jan. 23, 2004, 118 Stat. 434, provided that: “Except as otherwise provided in this section [enacting section 136w-8 of this title, amending this section and sections 136a-1, 136x, and 136y of this title, and enacting provisions set out as notes under sections 136 of this title and section 346a of Title 21, Food and Drugs] and the amendments made by this section, this section and the amendments made by this section take effect on the date that is 60 days after the date of enactment of this Act [Jan. 23, 2004].”

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Section 2(b) of Pub. L. 95-396 provided that: “The amendment to section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act [subsec. (c)(1)(D) of this section] made by [subsec. (a)(1) of] this section shall apply with respect to all applications for registration approved after the date of enactment of this Act [Sept. 30, 1978].”

EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

BIOLOGICAL PESTICIDE HANDLING STUDY

Section 1498 of Pub. L. 101-624 provided that:

“(a) STUDY.—Not later than September 30, 1992, the National Academy of Sciences shall conduct a study of the biological control programs and registration procedures utilized by the Food and Drug Administration, the Animal and Plant Health Inspection Service, and the Environmental Protection Agency.

“(b) DEVELOPMENT OF PROCEDURES.—Not later than 1 year after the completion of the study under subsection (a), the agencies and offices described in such subsection shall develop and implement a common process for reviewing and approving biological control applications that are submitted to such agencies and offices that shall be based on the study conducted under such subsection and the recommendation of the National Academy of Sciences, and other public comment.”

EDUCATION, STUDY, AND REPORT

Pub. L. 100-478, title I, § 1010, Oct. 7, 1988, 102 Stat. 2313, provided that:

“(a) EDUCATION.—The Administrator of the Environmental Protection Agency in cooperation with the Secretary of Agriculture and the Secretary of the Interior, promptly upon enactment of this Act [Oct. 7, 1988], shall conduct a program to inform and educate fully persons engaged in agricultural food and fiber commodity production of any proposed pesticide labeling program or requirements that may be imposed by the Ad-

ministrator in compliance with the Endangered Species Act [of 1973] (16 U.S.C. 1531 et seq.). The Administrator also shall provide the public with notice of, and opportunity for comment on, the elements of any such program and requirements based on compliance with the Endangered Species Act [of 1973], including (but not limited to) an identification of any pesticides affected by the program; an explanation of the restriction or prohibition on the user or applicator of any such pesticide; an identification of those geographic areas affected by any pesticide restriction or prohibition; an identification of the effects of any restricted or prohibited pesticide on endangered or threatened species; and an identification of the endangered or threatened species along with a general description of the geographic areas in which such species are located wherein the application of a pesticide will be restricted, prohibited, or its use otherwise limited, unless the Secretary of the Interior determines that the disclosure of such information may create a substantial risk of harm to such species or its habitat.

“(b) STUDY.—The Administrator of the Environmental Protection Agency, jointly with the Secretary of Agriculture and the Secretary of the Interior, shall conduct a study to identify reasonable and prudent means available to the Administrator to implement the endangered species pesticides labeling program which would comply with the Endangered Species Act of 1973, as amended, and which would allow persons to continue production of agricultural food and fiber commodities. Such study shall include investigation by the Administrator of the best available methods to develop maps and the best available alternatives to mapping as means of identifying those circumstances in which use of pesticides may be restricted; identification of alternatives to prohibitions on pesticide use, including, but not limited to, alternative pesticides and application methods and other agricultural practices which can be used in lieu of any pesticides whose use may be restricted by the labeling program; examination of methods to improve coordination among the Environmental Protection Agency, Department of Agriculture, and Department of the Interior in administration of the labeling program; and analysis of the means of implementing the endangered species pesticides labeling program or alternatives to such a program, if any, to promote the conservation of endangered or threatened species and to minimize the impacts to persons engaged in agricultural food and fiber commodity production and other affected pesticide users and applicators.

“(c) REPORT.—The Administrator of the Environmental Protection Agency in cooperation with the Secretary of Agriculture and the Secretary of the Interior shall submit a report within one year of the date of enactment of this Act [Oct. 7, 1988], presenting the results of the study conducted pursuant to subsection (b) of this section to the Committee on Merchant Marine and Fisheries and the Committee on Agriculture of the United States House of Representatives, and the Committee on Environment and Public Works and the Committee on Agriculture, Nutrition, and Forestry of the United States Senate.”

§ 136a-1. Reregistration of registered pesticides

(a) General rule

The Administrator shall reregister, in accordance with this section, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide as to which the Administrator has determined, after November 1, 1984, and before the effective date of this section, that—

(1) there are no outstanding data requirements; and

(2) the requirements of section 136a(c)(5) of this title have been satisfied.

94-140, §10, Nov. 28, 1975, 89 Stat. 754; Pub. L. 95-396, §10, Sept. 30, 1978, 92 Stat. 828; Pub. L. 100-532, title VIII, §801(d), (q)(1)(D), Oct. 25, 1988, 102 Stat. 2681, 2683; Pub. L. 102-237, title X, §1006(b)(1), Dec. 13, 1991, 105 Stat. 1895.)

PRIOR PROVISIONS

A prior section 5 of act June 25, 1947, was classified to section 135c of this title prior to amendment of act June 25, 1947, by Pub. L. 92-516.

AMENDMENTS

1991—Subsecs. (b), (e), (f). Pub. L. 102-237 substituted “the Administrator” for “he” before “may” in subsec. (b), before “finds” in subsec. (e), and before “may” in subsec. (f).

1988—Subsec. (f). Pub. L. 100-532, §801(q)(1)(D), substituted “136i” for “136b”.

Subsec. (g). Pub. L. 100-532, §801(d), substituted “require. Such pesticide” for “require: *Provided*, That such pesticide”.

1978—Subsec. (a). Pub. L. 95-396, §10(1), provided for review of application, issuance or nonissuance of experimental use permit within prescribed period including reasons for denial, correction of application, and waiver of conditions and substituted provision for filing an application for experimental use permit at any time for prior provision for filing at the time of or before or after an application for registration is filed.

Subsec. (f). Pub. L. 95-396, §10(2), substituted in first sentence “shall” for “may” where first appearing.

1975—Subsec. (g). Pub. L. 94-140 added subsec. (g).

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

§ 136d. Administrative review; suspension

(a) Existing stocks and information

(1) Existing stocks

The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under this section, or section 136a or 136a-1 of this title, to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter.

(2) Information

If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator.

(b) Cancellation and change in classification

If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the Administrator's intent either—

(1) to cancel its registration or to change its classification together with the reasons (in-

cluding the factual basis) for the Administrator's action, or

(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Such notice shall be sent to the registrant and made public. In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period notwithstanding the foregoing 60-day time requirement. The time requirements imposed by the preceding 3 sentences may be waived or modified to the extent agreed upon by the Administrator and the Secretary. Notwithstanding any other provision of this subsection and section 136w(d) of this title, in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, then upon such a finding the Administrator may waive the requirement of notice to and consultation with the Secretary of Agriculture pursuant to this subsection and of submission to the Scientific Advisory Panel pursuant to section 136w(d) of this title and proceed in accordance with subsection (c) of this section. When a public health use is affected, the Secretary of Health and Human Services should provide available benefits and use information, or an analysis thereof, in accordance with the procedures followed and subject to the same conditions as the Secretary of Agriculture in the case of agricultural pesticides. The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or to the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final. In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall in-

clude among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such impact.

(c) Suspension

(1) Order

If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, the Administrator may, by order, suspend the registration of the pesticide immediately. Except as provided in paragraph (3), no order of suspension may be issued under this subsection unless the Administrator has issued, or at the same time issues, a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) of this section. Except as provided in paragraph (3), the Administrator shall notify the registrant prior to issuing any suspension order. Such notice shall include findings pertaining to the question of "imminent hazard". The registrant shall then have an opportunity, in accordance with the provisions of paragraph (2), for an expedited hearing before the Administrator on the question of whether an imminent hazard exists.

(2) Expedite hearing

If no request for a hearing is submitted to the Administrator within five days of the registrant's receipt of the notification provided for by paragraph (1), the suspension order may be issued and shall take effect and shall not be reviewable by a court. If a hearing is requested, it shall commence within five days of the receipt of the request for such hearing unless the registrant and the Administrator agree that it shall commence at a later time. The hearing shall be held in accordance with the provisions of subchapter II of chapter 5 of title 5, except that the presiding officer need not be a certified administrative law judge. The presiding officer shall have ten days from the conclusion of the presentation of evidence to submit recommended findings and conclusions to the Administrator, who shall then have seven days to render a final order on the issue of suspension.

(3) Emergency order

Whenever the Administrator determines that an emergency exists that does not permit the Administrator to hold a hearing before suspending, the Administrator may issue a suspension order in advance of notification to the registrant. The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) of this section and the Administrator shall proceed to issue the notice under subsection (b) of this section within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) of this section within 90 days of issuing an emergency order, the emer-

gency order shall expire. In the case of an emergency order, paragraph (2) shall apply except that (A) the order of suspension shall be in effect pending the expeditious completion of the remedies provided by that paragraph and the issuance of a final order on suspension, and (B) no party other than the registrant and the Administrator shall participate except that any person adversely affected may file briefs within the time allotted by the Agency's rules. Any person so filing briefs shall be considered a party to such proceeding for the purposes of section 136n(b) of this title.

(4) Judicial review

A final order on the question of suspension following a hearing shall be reviewable in accordance with section 136n of this title, notwithstanding the fact that any related cancellation proceedings have not been completed. Any order of suspension entered prior to a hearing before the Administrator shall be subject to immediate review in an action by the registrant or other interested person with the concurrence of the registrant in an appropriate district court, solely to determine whether the order of suspension was arbitrary, capricious or an abuse of discretion, or whether the order was issued in accordance with the procedures established by law. The effect of any order of the court will be only to stay the effectiveness of the suspension order, pending the Administrator's final decision with respect to cancellation or change in classification. This action may be maintained simultaneously with any administrative review proceedings under this section. The commencement of proceedings under this paragraph shall not operate as a stay of order, unless ordered by the court.

(d) Public hearings and scientific review

In the event a hearing is requested pursuant to subsection (b) of this section or determined upon by the Administrator pursuant to subsection (b) of this section, such hearing shall be held after due notice for the purpose of receiving evidence relevant and material to the issues raised by the objections filed by the applicant or other interested parties, or to the issues stated by the Administrator, if the hearing is called by the Administrator rather than by the filing of objections. Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Hearing Examiner shall issue a subpoena to compel testimony or production of documents from any person. The Hearing Examiner shall be guided by the principles of the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, the subpoena may be enforced by an appropriate United States district court in accordance with the principles stated herein. Upon the request of any party to a public hearing and when in the Hearing Examiner's judgment it is necessary or desirable, the Hearing Examiner shall at any time before the hearing record is closed refer to a Committee of the National Academy of Sciences the relevant ques-

tions of scientific fact involved in the public hearing. No member of any committee of the National Academy of Sciences established to carry out the functions of this section shall have a financial or other conflict of interest with respect to any matter considered by such committee. The Committee of the National Academy of Sciences shall report in writing to the Hearing Examiner within 60 days after such referral on these questions of scientific fact. The report shall be made public and shall be considered as part of the hearing record. The Administrator shall enter into appropriate arrangements with the National Academy of Sciences to assure an objective and competent scientific review of the questions presented to Committees of the Academy and to provide such other scientific advisory services as may be required by the Administrator for carrying out the purposes of this subchapter. As soon as practicable after completion of the hearing (including the report of the Academy) but not later than 90 days thereafter, the Administrator shall evaluate the data and reports before the Administrator and issue an order either revoking the Administrator's notice of intention issued pursuant to this section, or shall issue an order either canceling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. Such order shall be based only on substantial evidence of record of such hearing and shall set forth detailed findings of fact upon which the order is based.

(e) Conditional registration

(1) The Administrator shall issue a notice of intent to cancel a registration issued under section 136a(c)(7) of this title if (A) the Administrator, at any time during the period provided for satisfaction of any condition imposed, determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed, or (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met. The Administrator may permit the continued sale and use of existing stocks of a pesticide whose conditional registration has been canceled under this subsection to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter and will not have unreasonable adverse effects on the environment.

(2) A cancellation proposed under this subsection shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to cancel unless during that time a request for hearing is made by a person adversely affected by the notice. If a hearing is requested, a hearing shall be conducted under subsection (d) of this section. The only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the

disposition of existing stocks is consistent with this subchapter. A decision after completion of such hearing shall be final. Notwithstanding any other provision of this section, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing.

(f) General provisions

(1) Voluntary cancellation

(A) A registrant may, at any time, request that a pesticide registration of the registrant be canceled or amended to terminate one or more pesticide uses.

(B) Before acting on a request under subparagraph (A), the Administrator shall publish in the Federal Register a notice of the receipt of the request and provide for a 30-day period in which the public may comment.

(C) In the case of a pesticide that is registered for a minor agricultural use, if the Administrator determines that the cancellation or termination of uses would adversely affect the availability of the pesticide for use, the Administrator—

(i) shall publish in the Federal Register a notice of the receipt of the request and make reasonable efforts to inform persons who so use the pesticide of the request; and

(ii) may not approve or reject the request until the termination of the 180-day period beginning on the date of publication of the notice in the Federal Register, except that the Administrator may waive the 180-day period upon the request of the registrant or if the Administrator determines that the continued use of the pesticide would pose an unreasonable adverse effect on the environment.

(D) Subject to paragraph (3)(B), after complying with this paragraph, the Administrator may approve or deny the request.

(2) Publication of notice

A notice of denial of registration, intent to cancel, suspension, or intent to suspend issued under this subchapter or a notice issued under subsection (c)(4) or (d)(5)(A) of section 136a-1 of this title shall be published in the Federal Register and shall be sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Administrator. If the mailed notice is returned to the Administrator as undeliverable at that address, if delivery is refused, or if the Administrator otherwise is unable to accomplish delivery of the notice to the registrant or applicant after making reasonable efforts to do so, the notice shall be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

(3) Transfer of registration of pesticides registered for minor agricultural uses

In the case of a pesticide that is registered for a minor agricultural use:

(A) During the 180-day period referred to in paragraph (1)(C)(ii), the registrant of the pesticide may notify the Administrator of an agreement between the registrant and a

person or persons (including persons who so use the pesticide) to transfer the registration of the pesticide, in lieu of canceling or amending the registration to terminate the use.

(B) An application for transfer of registration, in conformance with any regulations the Administrator may adopt with respect to the transfer of the pesticide registrations, must be submitted to the Administrator within 30 days of the date of notification provided pursuant to subparagraph (A). If such an application is submitted, the Administrator shall approve the transfer and shall not approve the request for voluntary cancellation or amendment to terminate use unless the Administrator determines that the continued use of the pesticide would cause an unreasonable adverse effect on the environment.

(C) If the Administrator approves the transfer and the registrant transfers the registration of the pesticide, the Administrator shall not cancel or amend the registration to delete the use or rescind the transfer of the registration, during the 180-day period beginning on the date of the approval of the transfer unless the Administrator determines that the continued use of the pesticide would cause an unreasonable adverse effect on the environment.

(D) The new registrant of the pesticide shall assume the outstanding data and other requirements for the pesticide that are pending at the time of the transfer.

(4) Utilization of data for voluntarily canceled pesticide

When an application is filed with the Administrator for the registration of a pesticide for a minor use and another registrant subsequently voluntarily cancels its registration for an identical or substantially similar pesticide for an identical or substantially similar use, the Administrator shall process, review, and evaluate the pending application as if the voluntary cancellation had not yet taken place except that the Administrator shall not take such action if the Administrator determines that such minor use may cause an unreasonable adverse effect on the environment. In order to rely on this subsection, the applicant must certify that it agrees to satisfy any outstanding data requirements necessary to support the reregistration of the pesticide in accordance with the data submission schedule established by the Administrator.

(g) Notice for stored pesticides with canceled or suspended registrations

(1) In general

Any producer or exporter of pesticides, registrant of a pesticide, applicant for registration of a pesticide, applicant for or holder of an experimental use permit, commercial applicator, or any person who distributes or sells any pesticide, who possesses any pesticide which has had its registration canceled or suspended under this section shall notify the Administrator and appropriate State and local officials of—

(A) such possession,

(B) the quantity of such pesticide such person possesses, and

(C) the place at which such pesticide is stored.

(2) Copies

The Administrator shall transmit a copy of each notice submitted under this subsection to the regional office of the Environmental Protection Agency which has jurisdiction over the place of pesticide storage identified in the notice.

(h) Judicial review

Final orders of the Administrator under this section shall be subject to judicial review pursuant to section 136n of this title.

(June 25, 1947, ch. 125, § 6, as added Pub. L. 92-516, § 2, Oct. 21, 1972, 86 Stat. 984; amended Pub. L. 94-140, § 1, Nov. 28, 1975, 89 Stat. 751; Pub. L. 95-251, § 2(a)(2), Mar. 27, 1978, 92 Stat. 183; Pub. L. 95-396, §§ 11, 12, Sept. 30, 1978, 92 Stat. 828; Pub. L. 98-620, title IV, § 402(4)(A), Nov. 8, 1984, 98 Stat. 3357; Pub. L. 100-532, title II, § 201, title IV, § 404, title VIII, § 801(e), (q)(2)(B), Oct. 25, 1988, 102 Stat. 2668, 2673, 2681, 2683; Pub. L. 101-624, title XIV, § 1494, Nov. 28, 1990, 104 Stat. 3628; Pub. L. 102-237, title X, § 1006(a)(5), (b)(1), (2), (3)(C)-(E), Dec. 13, 1991, 105 Stat. 1895, 1896; Pub. L. 104-170, title I, §§ 102, 106(a), title II, §§ 210(g), (h), 233, Aug. 3, 1996, 110 Stat. 1489, 1491, 1500, 1509.)

CODIFICATION

“Subchapter II of chapter 5 of title 5”, referred to in subsec. (c)(2), was in the original “subchapter II of Title 5”, and was editorially changed to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 6 of act June 25, 1947, was classified to section 135d of this title prior to amendment of act June 25, 1947, by Pub. L. 92-516.

AMENDMENTS

1996—Subsec. (a). Pub. L. 104-170, § 106(a)(1), substituted “Existing stocks and information” for “Cancellation after five years” in heading.

Subsec. (a)(1). Pub. L. 104-170, § 106(a)(2), amended heading and text generally. Prior to amendment, text read as follows: “The Administrator shall cancel the registration of any pesticide at the end of the five-year period which begins on the date of its registration (or at the end of any five year period thereafter) unless the registrant, or other interested person with the concurrence of the registrant, before the end of such period, requests in accordance with regulations prescribed by the Administrator that the registration be continued in effect. The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is canceled under this subsection or subsection (b) of this section to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter and will not have unreasonable adverse effects on the environment. The Administrator shall publish in the Federal Register, at least 30 days prior to the expiration of such five-year period, notice that the registration will be canceled if the registrant or other interested person with the concurrence of the registrant does not request that the registration be continued in effect.”

Subsec. (b). Pub. L. 104-170, § 233, inserted “When a public health use is affected, the Secretary of Health

and Human Services should provide available benefits and use information, or an analysis thereof, in accordance with the procedures followed and subject to the same conditions as the Secretary of Agriculture in the case of agricultural pesticides." before "The proposed action shall become final".

Subsec. (c)(1). Pub. L. 104-170, §102(a), amended second sentence generally. Prior to amendment, second sentence read as follows: "No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of the Administrator's intention to cancel the registration or change the classification of the pesticide."

Subsec. (c)(3). Pub. L. 104-170, §102(b), inserted after first sentence "The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) of this section and the Administrator shall proceed to issue the notice under subsection (b) of this section within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) of this section within 90 days of issuing an emergency order, the emergency order shall expire." and substituted "In the case of an emergency order" for "In that case".

Subsec. (f)(1)(C)(ii). Pub. L. 104-170, §210(g)(1), substituted "180-day" for "90-day" in two places.

Subsec. (f)(3)(A). Pub. L. 104-170, §210(g)(2), substituted "180-day" for "90-day".

Subsec. (f)(4). Pub. L. 104-170, §210(h), added par. (4). 1991—Subsec. (a)(1). Pub. L. 102-237, §1006(b)(1), substituted "the Administrator" for "he" before "may specify" and before "determines".

Subsec. (a)(2). Pub. L. 102-237, §1006(b)(3)(C), substituted "the registrant" for "he" before "shall".

Subsec. (b). Pub. L. 102-237, §1006(b)(1), (2), substituted "the Administrator's" for "his" in introductory provisions and par. (1), and "the Administrator" for "he" before "shall publish" in last sentence.

Subsec. (c)(1). Pub. L. 102-237, §1006(b)(1), (2), substituted "the Administrator" for "he" before "may" and "the Administrator's" for "his" before "intention".

Subsec. (c)(3). Pub. L. 102-237, §1006(b)(1), (3)(D), substituted "the Administrator" for "he" before "may" and "the Administrator" for "him" after "permit".

Subsec. (d). Pub. L. 102-237, §1006(b)(2), (3)(E), in penultimate sentence substituted "the Administrator's" for "his" and "the Administrator" for "him" before "and issue".

Subsec. (f)(3)(B). Pub. L. 102-237, §1006(a)(5), substituted "adverse effect" for "adverse affect".

1990—Subsec. (f)(1). Pub. L. 101-624, §1494(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "A registrant at any time may request that any of its pesticide registrations be canceled or be amended to delete one or more uses. Before acting on such request, the Administrator shall publish in the Federal Register a notice of the receipt of the request. Thereafter, the Administrator may approve such a request."

Subsec. (f)(3). Pub. L. 101-624, §1494(2), added par. (3).

1988—Subsec. (a)(1). Pub. L. 100-532, §801(e)(1), substituted "effect. The Administrator" for "effect: *Provided*, That the Administrator".

Subsec. (c). Pub. L. 100-532, §801(e)(2)-(4), in par. (1) directed that undesignated paragraph beginning "Except as provided" be run into sentence ending "of the pesticide." and substituted "before the Administrator" for "before the Agency", in par. (2) substituted "submitted to the Administrator" for "submitted to the Agency" and "and the Administrator" for "and the Agency", and in par. (3) substituted "(A)" for "(i)", "and the Administrator" for "and the Agency", and "(B)" for "(ii)".

Subsec. (e). Pub. L. 100-532, §801(e)(5), (6), in par. (1), substituted "met. The Administrator" for "met: *Provided*, That the Administrator", and in par. (2), substituted "section. The only" for "section: *Provided*, That the only".

Subsec. (f). Pub. L. 100-532, §201, added subsec. (f). Former subsec. (f) redesignated (h).

Subsec. (f)(2). Pub. L. 100-532, §801(q)(2)(B), made a technical amendment to the reference to section 136a-1 of this title to reflect the renumbering of the corresponding section of the original act.

Subsec. (g). Pub. L. 100-532, §404, added subsec. (g).

Subsec. (h). Pub. L. 100-532, §201, redesignated former subsec. (f) as (h).

1984—Subsec. (c)(4). Pub. L. 98-620 struck out provisions requiring petitions to review orders on the issue of suspension to be advanced on the docket of the court of appeals.

1978—Subsec. (b). Pub. L. 95-396, §11, required the Administrator, in taking any final action under subsec. (b), to consider restricting a pesticide's use or uses as an alternative to cancellation and to fully explain the reasons for the restrictions.

Subsec. (c)(2). Pub. L. 95-251 substituted "administrative law judge" for "hearing examiner".

Subsecs. (e), (f). Pub. L. 95-396, §12, added subsec. (e) and redesignated former subsec. (e) as (f).

1975—Subsec. (b). Pub. L. 94-140 established criteria which Administrator must use in determining the issuance of a suspension of registration notice and the time periods relating to such notice, set forth required procedures to be followed by Administrator prior to publication of such notice, required procedures when the Secretary elects to comment or fails to comment on suspension notice, waiver or modification of time periods in specified required procedures, required procedures for waiver of notice and consent by Secretary for suspension of registration, and established criteria for Secretary taking any final action.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98-620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98-620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

§ 136e. Registration of establishments

(a) Requirement

No person shall produce any pesticide subject to this subchapter or active ingredient used in producing a pesticide subject to this subchapter in any State unless the establishment in which it is produced is registered with the Administrator. The application for registration of any establishment shall include the name and address of the establishment and of the producer who operates such establishment.

(b) Registration

Whenever the Administrator receives an application under subsection (a) of this section, the Administrator shall register the establishment and assign it an establishment number.

(c) Information required

(1) Any producer operating an establishment registered under this section shall inform the Administrator within 30 days after it is registered of the types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides—

(A) which the producer is currently producing;

(II) owned any quantity of the pesticide for purposes of—
 (aa) distributing or selling it; or
 (bb) further processing it for distribution or sale directly to an end user;

suffered a loss by reason of the suspension or cancellation of the pesticide; and

(iv) the Administrator determines on the basis of a claim of loss submitted to the Administrator by the person, that the seller—

(I) did not provide the notice specified in subparagraph (A) to such person; and

(II) is and will continue to be unable to provide reimbursement to such person, as provided under subparagraph (A), for the loss referred to in clause (iii), as a result of the insolvency or bankruptcy of the seller and the seller's resulting inability to provide such reimbursement;

the person shall be entitled to an indemnity payment under this subsection for such quantity of the pesticide.

(C) If an indemnity payment is made by the United States under this paragraph, the United States shall be subrogated to any right that would otherwise be held under this paragraph by a seller who is unable to make a reimbursement in accordance with this paragraph with regard to reimbursements that otherwise would have been made by the seller.

(3) Source

Any payment required to be made under paragraph (1) or (2) shall be made from the appropriation provided under section 1304 of title 31.

(4) Administrative settlement

An administrative settlement of a claim for such indemnity may be made in accordance with the third paragraph of section 2414 of title 28 and shall be regarded as if it were made under that section for purposes of section 1304 of title 31.

(c) Amount of payment

(1) In general

The amount of an indemnity payment under subsection (a) or (b) to any person shall be determined on the basis of the cost of the pesticide owned by the person (other than the cost of transportation, if any) immediately before the issuance of the notice to the registrant referred to in subsection (a)(1)(A), (b)(1)(A), or (b)(2)(B)(i), except that in no event shall an indemnity payment to any person exceed the fair market value of the pesticide owned by the person immediately before the issuance of the notice.

(2) Special rule

Notwithstanding any other provision of this subchapter, the Administrator may provide a reasonable time for use or other disposal of the pesticide. In determining the quantity of any pesticide for which indemnity shall be paid under this section, proper adjustment shall be made for any pesticide used or otherwise disposed of by the owner.

(June 25, 1947, ch. 125, §15, as added Pub. L. 92-516, §2, Oct. 21, 1972, 86 Stat. 993; amended

Pub. L. 100-532, title V, §501(a), Oct. 25, 1988, 102 Stat. 2674.)

AMENDMENTS

1988—Pub. L. 100-532 amended section generally, in subsec. (a), substituting provisions relating to general indemnification for provisions relating to requirements for payment, adding subsec. (b), and redesignating provisions of former subsec. (b), with further amendment, as subsec. (c).

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100-532, title V, §501(a), Oct. 25, 1988, 102 Stat. 2674, provided that amendment made by Pub. L. 100-532 is effective 180 days after Oct. 25, 1988.

EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

INTERIM PAYMENTS

Pub. L. 100-532, title V, §501(b), Oct. 25, 1988, 102 Stat. 2676, provided that:

“(1) **SOURCE.**—Any obligation of the Administrator to pay an indemnity arising under section 15 [this section], as it existed prior to the effective date of the amendment made by this section [see Effective Date of 1988 Amendment note above], shall be made from the appropriation provided under section 1304 of title 31, United States Code.

“(2) **ADMINISTRATIVE SETTLEMENT.**—An administrative settlement of a claim for such indemnity may be made in accordance with the third paragraph of section 2414 of title 28, United States Code, and shall be regarded as if it were made under that section for purposes of section 1304 of title 31, United States Code.”

§ 136n. Administrative procedure; judicial review

(a) District court review

Except as otherwise provided in this subchapter, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States.

(b) Review by court of appeals

In the case of actual controversy as to the validity of any order issued by the Administrator following a public hearing, any person who will be adversely affected by such order and who had been a party to the proceedings may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the Administrator's order, as provided in section 2112 of title 28. Upon the filing of such petition the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole. The judgment of the court af-

firming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

(c) Jurisdiction of district courts

The district courts of the United States are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this subchapter.

(d) Notice of judgments

The Administrator shall, by publication in such manner as the Administrator may prescribe, give notice of all judgments entered in actions instituted under the authority of this subchapter.

(June 25, 1947, ch. 125, §16, as added Pub. L. 92-516, §2, Oct. 21, 1972, 86 Stat. 994; amended Pub. L. 98-620, title IV, §402(4)(C), Nov. 8, 1984, 98 Stat. 3357; Pub. L. 100-532, title VIII, §801(i), Oct. 25, 1988, 102 Stat. 2682; Pub. L. 102-237, title X, §1006(b)(1), (2), (3)(P), Dec. 13, 1991, 105 Stat. 1895, 1896.)

AMENDMENTS

1991—Subsec. (b). Pub. L. 102-237, §1006(b)(1), (2), (3)(P), substituted “the Administrator” for “he” before “based”, “the Administrator’s” for “his”, and “the Administrator” for “him” after “designated by”.

Subsec. (d). Pub. L. 102-237, §1006(b)(1), substituted “the Administrator” for “he” before “may”.

1988—Subsec. (a). Pub. L. 100-532 amended subsec. (a) generally. Prior to amendment, subsec. (a) read as follows: “Except as is otherwise provided in this subchapter, Agency refusals to cancel or suspend registrations or change classifications not following a hearing and other final Agency actions not committed to Agency discretion by law are judicially reviewable in the district courts.”

1984—Subsec. (b). Pub. L. 98-620 struck out provisions requiring the court to advance on the docket and expedite the disposition of all cases filed pursuant to this section.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98-620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98-620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

§ 136o. Imports and exports

(a) Pesticides and devices intended for export

Notwithstanding any other provision of this subchapter, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this subchapter—

(1) when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pes-

ticides and devices and active ingredients used in producing pesticides shall be subject to sections 136(p), 136(q)(1)(A), (C), (D), (E), (G), and (H), 136(q)(2)(A), (B), (C)(i) and (iii), and (D), 136e, and 136f of this title; and

(2) in the case of any pesticide other than a pesticide registered under section 136a or sold under section 136d(a)(1) of this title, if, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this subchapter.

A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

(b) Cancellation notices furnished to foreign governments

Whenever a registration, or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies. Such notification shall, upon request, include all information related to the cancellation or suspension of the registration of the pesticide and information concerning other pesticides that are registered under section 136a of this title and that could be used in lieu of such pesticide.

(c) Importation of pesticides and devices

(1) In general

The Secretary of the Treasury shall notify the Administrator of the arrival of pesticides and devices and shall deliver to the Administrator, upon the Administrator’s request, samples of pesticides or devices which are being imported into the United States, giving notice to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. If it appears from the examination of a sample that it is adulterated, or misbranded or otherwise violates the provisions set forth in this subchapter, or is otherwise injurious to health or the environment, the pesticide or device may be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any pesticide or device refused delivery which shall not be exported by the consignee within 90 days from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe. The Secretary of the Treasury may deliver to the consignee such pesticide or device pending examination and decision in the matter on execution of bond for the amount of the full invoice value of such pesticide or device, together with the duty thereon, and on refusal to return such pesticide or device for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of said bond. All charges for storage, cartage, and labor on pesticides or devices which are refused admission

into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(June 25, 1938, ch. 675, §406, 52 Stat. 1049; Pub. L. 85-929, §3(c), Sept. 6, 1958, 72 Stat. 1785; Pub. L. 86-618, title I, §103(a)(1), July 12, 1960, 74 Stat. 398.)

AMENDMENTS

1960—Pub. L. 86-618 repealed subsec. (b) which required Secretary to promulgate regulations for listing of coal-tar colors.

1958—Subsec. (a). Pub. L. 85-929 substituted “clause (2)(A)” for “clause (2)” in first sentence.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86-618, see section 202 of Pub. L. 86-618, set out as a note under section 379e of this title.

EFFECTIVE DATE OF NEMATOCIDE, PLANT REGULATOR, DEFOLIANT, AND DESICCANT AMENDMENT OF 1959

Effective date of subsec. (a) as in force prior to July 22, 1954, with respect to particular commercial use of a nematocide, plant regulator, defoliant, or desiccant in or on a raw agricultural commodity made before Jan. 1, 1958, see section 3(b) of Pub. L. 86-139, Aug. 7, 1959, 73 Stat. 288.

EFFECTIVE DATE OF 1958 AMENDMENT

For effective date of amendment by Pub. L. 85-929, see section 6(b), (c) of Pub. L. 85-929, set out as a note under section 342 of this title.

TRANSFER OF FUNCTIONS

Functions vested in Secretary of Health, Education, and Welfare [now Health and Human Services] in establishing tolerances for pesticide chemicals under this section together with authority to monitor compliance with tolerances and effectiveness of surveillance and enforcement and to provide technical assistance to States and conduct research under this chapter and section 201 et seq. of Title 42, The Public Health and Welfare, transferred to Administrator of Environmental Protection Agency by Reorg. Plan No. 3 of 1970, §2(a)(4), eff. Dec. 2, 1970, 35 F.R. 15623, 84 Stat. 2086, set out in the Appendix to Title 5, Government Organization and Employees.

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration to Federal Security Agency, see notes set out under section 321 of this title.

§ 346a. Tolerances and exemptions for pesticide chemical residues

(a) Requirement for tolerance or exemption

(1) General rule

Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 342(a)(2)(B) of this title unless—

(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

(B) an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

For the purposes of this section, the term “food”, when used as a noun without modifica-

tion, shall mean a raw agricultural commodity or processed food.

(2) Processed food

Notwithstanding paragraph (1)—

(A) if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 342(a)(2)(B) of this title despite the lack of a tolerance for the pesticide chemical residue in or on the processed food if the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 342(a)(2)(B) of this title.

(3) Residues of degradation products

If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, such a residue shall not be considered to be unsafe within the meaning of section 342(a)(2)(B) of this title despite the lack of a tolerance or exemption from the need for a tolerance for such residue in or on such food if—

(A) the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than, or of a greater significance than, any risk posed by dietary exposure to the precursor substance;

(B) either—

(i) a tolerance is in effect under this section for residues of the precursor substance in or on the food, and the combined level of residues of the degradation product and the precursor substance in or on the food is at or below the stoichiometrically equivalent level that would be permitted by the tolerance if the residue consisted only of the precursor substance rather than the degradation product; or

(ii) an exemption from the need for a tolerance is in effect under this section for residues of the precursor substance in or on the food; and

(C) the tolerance or exemption for residues of the precursor substance does not state

that it applies only to particular named substances and does not state that it does not apply to residues of the degradation product.

(4) Effect of tolerance or exemption

While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or containing any amount of such a residue be considered to be adulterated within the meaning of section 342(a)(1) of this title.

(b) Authority and standard for tolerance

(1) Authority

The Administrator may issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food—

(A) in response to a petition filed under subsection (d) of this section; or

(B) on the Administrator's own initiative under subsection (e) of this section.

As used in this section, the term “modify” shall not mean expanding the tolerance to cover additional foods.

(2) Standard

(A) General rule

(i) Standard

The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

(ii) Determination of safety

As used in this section, the term “safe”, with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(iii) Rule of construction

With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

(B) Tolerances for eligible pesticide chemical residues

(i) Definition

As used in this subparagraph, the term “eligible pesticide chemical residue” means a pesticide chemical residue as to which—

(I) the Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health (referred to in this section as a “nonthreshold effect”);

(II) the lifetime risk of experiencing the nonthreshold effect is appropriately

assessed by quantitative risk assessment; and

(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a “threshold effect”), the Administrator determines that the level of aggregate exposure is safe.

(ii) Determination of tolerance

Notwithstanding subparagraph (A)(i), a tolerance for an eligible pesticide chemical residue may be left in effect or modified under this subparagraph if—

(I) at least one of the conditions described in clause (iii) is met; and

(II) both of the conditions described in clause (iv) are met.

(iii) Conditions regarding use

For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) Use of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue.

(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

(iv) Conditions regarding risk

For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for such effect.

(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

(v) Review

Five years after the date on which the Administrator makes a determination to leave in effect or modify a tolerance under this subparagraph, and thereafter as the Administrator deems appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that a condition described in clause (iii)(I) or clause (iii)(II) continues to exist with respect to the tolerance and that the yearly and lifetime risks from aggregate exposure to such residue continue to comply with the limits specified in clause (iv). If the Administrator determines by such

date that such demonstration has not been made, the Administrator shall, not later than 180 days after the date of such determination, issue a regulation under subsection (e)(1) of this section to modify or revoke the tolerance.

(vi) Infants and children

Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

(C) Exposure of infants and children

In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

(i) shall assess the risk of the pesticide chemical residue based on—

(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

(II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

(III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity; and

(ii) shall—

(I) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and

(II) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.

(D) Factors

In establishing, modifying, leaving in effect, or revoking a tolerance or exemption

for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—

(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

(ii) the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies;

(iii) available information concerning the relationship of the results of such studies to human risk;

(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

(v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;

(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

(viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and

(ix) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

(E) Data and information regarding anticipated and actual residue levels

(i) Authority

In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the Food and Drug Administration.

(ii) Requirement

If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) of this section require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are

not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1) of this section, or an order under subsection (f)(2) of this section, as appropriate, to modify or revoke the tolerance.

(F) Percent of food actually treated

In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator—

(i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;

(ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group;

(iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator; and

(iv) provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

(3) Detection methods

(A) General rule

A tolerance for a pesticide chemical residue in or on a food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

(B) Detection limit

A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

(4) International standards

In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

(c) Authority and standard for exemptions

(1) Authority

The Administrator may issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food—

(A) in response to a petition filed under subsection (d) of this section; or

(B) on the Administrator's initiative under subsection (e) of this section.

(2) Standard

(A) General rule

(i) Standard

The Administrator may establish or leave in effect an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe. The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

(ii) Determination of safety

The term "safe", with respect to an exemption for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(B) Factors

In making a determination under this paragraph, the Administrator shall take into account, among other relevant considerations, the considerations set forth in subparagraphs (C) and (D) of subsection (b)(2) of this section.

(3) Limitation

An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

(A) that there is a practical method for detecting and measuring the levels of such pesticide chemical residue in or on food; or

(B) that there is no need for such method, and states the reasons for such determination in issuing the regulation establishing or modifying the exemption.

(d) Petition for tolerance or exemption

(1) Petitions and petitioners

Any person may file with the Administrator a petition proposing the issuance of a regulation—

(A) establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food; or

(B) establishing, modifying, or revoking an exemption from the requirement of a tolerance for such a residue.

(2) Petition contents

(A) Establishment

A petition under paragraph (1) to establish a tolerance or exemption for a pesticide

chemical residue shall be supported by such data and information as are specified in regulations issued by the Administrator, including—

(i)(I) an informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition; and

(II) a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice of filing of the petition to be published under this subsection and as part of a proposed or final regulation issued under this section;

(ii) the name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue;

(iii) data showing the recommended amount, frequency, method, and time of application of that pesticide chemical;

(iv) full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations;

(v) full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used;

(vi) a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed;

(vii) a proposed tolerance for the pesticide chemical residue, if a tolerance is proposed;

(viii) if the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food;

(ix) such information as the Administrator may require to make the determination under subsection (b)(2)(C) of this section;

(x) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects;

(xi) information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue;

(xii) practical methods for removing any amount of the residue that would exceed any proposed tolerance; and

(xiii) such other data and information as the Administrator requires by regulation to support the petition.

If information or data required by this subparagraph is available to the Administrator, the person submitting the petition may cite the availability of the information or data in lieu of submitting it. The Administrator

may require a petition to be accompanied by samples of the pesticide chemical with respect to which the petition is filed.

(B) Modification or revocation

The Administrator may by regulation establish the requirements for information and data to support a petition to modify or revoke a tolerance or to modify or revoke an exemption from the requirement for a tolerance.

(3) Notice

A notice of the filing of a petition that the Administrator determines has met the requirements of paragraph (2) shall be published by the Administrator within 30 days after such determination. The notice shall announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the petitioner's statement of why such a method is not needed. The notice shall include the summary required by paragraph (2)(A)(i)(I).

(4) Actions by the Administrator

(A) In general

The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator—

(i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance (which final regulation shall be issued without further notice and without further period for public comment);

(ii) issue a proposed regulation under subsection (e) of this section, and thereafter issue a final regulation under such subsection; or

(iii) issue an order denying the petition.

(B) Priorities

The Administrator shall give priority to petitions for the establishment or modification of a tolerance or exemption for a pesticide chemical residue that appears to pose a significantly lower risk to human health from dietary exposure than pesticide chemical residues that have tolerances in effect for the same or similar uses.

(C) Expedited review of certain petitions

(i) Date certain for review

If a person files a complete petition with the Administrator proposing the issuance of a regulation establishing a tolerance or exemption for a pesticide chemical residue that presents a lower risk to human health than a pesticide chemical residue for which a tolerance has been left in effect or modified under subsection (b)(2)(B) of this section, the Administrator shall complete action on such petition under this paragraph within 1 year.

(ii) Required determinations

If the Administrator issues a final regulation establishing a tolerance or exemp-

tion for a safer pesticide chemical residue under clause (i), the Administrator shall, not later than 180 days after the date on which the regulation is issued, determine whether a condition described in subclause (I) or (II) of subsection (b)(2)(B)(iii) of this section continues to exist with respect to a tolerance that has been left in effect or modified under subsection (b)(2)(B) of this section. If such condition does not continue to exist, the Administrator shall, not later than 180 days after the date on which the determination under the preceding sentence is made, issue a regulation under subsection (e)(1) of this section to modify or revoke the tolerance.

(e) Action on Administrator's own initiative

(1) General rule

The Administrator may issue a regulation—

(A) establishing, modifying, suspending under subsection (l)(3) of this section, or revoking a tolerance for a pesticide chemical or a pesticide chemical residue;

(B) establishing, modifying, suspending under subsection (l)(3) of this section, or revoking an exemption of a pesticide chemical residue from the requirement of a tolerance; or

(C) establishing general procedures and requirements to implement this section.

(2) Notice

Before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(f) Special data requirements

(1) Requiring submission of additional data

If the Administrator determines that additional data or information are reasonably required to support the continuation of a tolerance or exemption that is in effect under this section for a pesticide chemical residue on a food, the Administrator shall—

(A) issue a notice requiring the person holding the pesticide registrations associated with such tolerance or exemption to submit the data or information under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a(c)(2)(B)];

(B) issue a rule requiring that testing be conducted on a substance or mixture under section 4 of the Toxic Substances Control Act [15 U.S.C. 2603]; or

(C) publish in the Federal Register, after first providing notice and an opportunity for comment of not less than 60 days' duration, an order—

(i) requiring the submission to the Administrator by one or more interested persons of a notice identifying the person or persons who will submit the required data and information;

(ii) describing the type of data and information required to be submitted to the Administrator and stating why the data and information could not be obtained under the authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a(c)(2)(B)] or section 4 of the Toxic Substances Control Act [15 U.S.C. 2603];

(iii) describing the reports of the Administrator required to be prepared during and after the collection of the data and information;

(iv) requiring the submission to the Administrator of the data, information, and reports referred to in clauses (ii) and (iii); and

(v) establishing dates by which the submissions described in clauses (i) and (iv) must be made.

The Administrator may under subparagraph (C) revise any such order to correct an error. The Administrator may under this paragraph require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

(2) Noncompliance

If a submission required by a notice issued in accordance with paragraph (1)(A), a rule issued under paragraph (1)(B), or an order issued under paragraph (1)(C) is not made by the time specified in such notice, rule, or order, the Administrator may by order published in the Federal Register modify or revoke the tolerance or exemption in question. In any review of such an order under subsection (g)(2) of this section, the only material issue shall be whether a submission required under paragraph (1) was not made by the time specified.

(g) Effective date, objections, hearings, and administrative review

(1) Effective date

A regulation or order issued under subsection (d)(4), (e)(1), or (f)(2) of this section shall take effect upon publication unless the regulation or order specifies otherwise. The Administrator may stay the effectiveness of the regulation or order if, after issuance of such regulation or order, objections are filed with respect to such regulation or order pursuant to paragraph (2).

(2) Further proceedings

(A) Objections

Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C) of this section, any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under subsection (d)(1) of this section, a copy of each objection filed by a person other than the petitioner shall be served by the Administrator on the petitioner.

(B) Hearing

An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections. The presiding officer in such a hearing may authorize a party to obtain discovery from other persons and may upon a showing of good cause made by a party issue a subpoena to compel testimony or production of documents from any person. The presiding officer shall be governed by the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, such a subpoena may be enforced by a Federal district court.

(C) Final decision

As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under subparagraph (B), such order and any revision to the regulation or prior order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at such hearing, and shall set forth in detail the findings of facts and the conclusions of law or policy upon which the order or regulation is based.

(h) Judicial review**(1) Petition**

In a case of actual controversy as to the validity of any regulation issued under subsection (e)(1)(C) of this section, or any order issued under subsection (f)(1)(C) or (g)(2)(C) of this section, or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

(2) Record and jurisdiction

A copy of the petition under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title

28. Upon the filing of such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part. As to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

(3) Additional evidence

If a party applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Administrator, the court may order that the additional evidence (and evidence in rebuttal thereof) shall be taken before the Administrator in the manner and upon the terms and conditions the court deems proper. The Administrator may modify prior findings as to the facts by reason of the additional evidence so taken and may modify the order or regulation accordingly. The Administrator shall file with the court any such modified finding, order, or regulation.

(4) Final judgment; Supreme Court review

The judgment of the court affirming or setting aside, in whole or in part, any regulation or any order and any regulation which is the subject of such an order shall be final, subject to review by the Supreme Court of the United States as provided in section 1254 of title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

(5) Application

Any issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law.

(i) Confidentiality and use of data**(1) General rule**

Data and information that are or have been submitted to the Administrator under this section or section 348 of this title in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a, 136h].

(2) Exceptions**(A) In general**

Data and information that are entitled to confidential treatment under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

- (i) employees of the United States authorized by the Administrator to examine such data and information in the carrying out of their official duties under this chapter or other Federal statutes intended to protect the public health; or

(ii) contractors with the United States authorized by the Administrator to examine such data and information in the carrying out of contracts under this chapter or such statutes.

(B) Congress

This subsection does not authorize the withholding of data or information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(3) Summaries

Notwithstanding any provision of this subsection or other law, the Administrator may publish the informative summary required by subsection (d)(2)(A)(i) of this section and may, in issuing a proposed or final regulation or order under this section, publish an informative summary of the data relating to the regulation or order.

(j) Status of previously issued regulations

(1) Regulations under section 346

Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance with section 371(e) of this title, under the authority of section 346(a)¹ of this title upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (d) and (e) of this section, and shall be subject to review under subsection (q) of this section.

(2) Regulations under section 348

Regulations that established tolerances for substances that are pesticide chemical residues in or on processed food, or that otherwise stated the conditions under which such pesticide chemicals could be safely used, and that were issued under section 348 of this title on or before August 3, 1996, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsection (d) or (e) of this section, and shall be subject to review under subsection (q) of this section.

(3) Regulations under section 346a

Regulations that established tolerances or exemptions under this section that were issued on or before August 3, 1996, shall remain in effect unless modified or revoked under subsection (d) or (e) of this section, and shall be subject to review under subsection (q) of this section.

(4) Certain substances

With respect to a substance that is not included in the definition of the term "pesticide chemical" under section 321(q)(1) of this title but was so included on the day before October 30, 1998, the following applies as of October 30, 1998:

(A) Notwithstanding paragraph (2), any regulation applying to the use of the sub-

stance that was in effect on the day before October 30, 1998, and was on such day deemed in such paragraph to have been issued under this section, shall be considered to have been issued under section 348 of this title.

(B) Notwithstanding paragraph (3), any regulation applying to the use of the substance that was in effect on such day and was issued under this section (including any such regulation issued before August 3, 1996) is deemed to have been issued under section 348 of this title.

(k) Transitional provision

If, on the day before August 3, 1996, a substance that is a pesticide chemical was, with respect to a particular pesticidal use of the substance and any resulting pesticide chemical residue in or on a particular food—

(1) regarded by the Administrator or the Secretary as generally recognized as safe for use within the meaning of the provisions of subsection (a) of this section or section 321(s) of this title as then in effect; or

(2) regarded by the Secretary as a substance described by section 321(s)(4) of this title;

such a pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of August 3, 1996. The Administrator shall by regulation indicate which substances are described by this subsection. Any exemption under this subsection may be modified or revoked as if it had been issued under subsection (c) of this section.

(l) Harmonization with action under other laws

(1) Coordination with FIFRA

To the extent practicable and consistent with the review deadlines in subsection (q) of this section, in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.].

(2) Revocation of tolerance or exemption following cancellation of associated registrations

If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, cancels the registration of each pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall revoke any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) of this section shall apply to actions taken under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after—

(A) the date by which each such cancellation of a registration has become effective; or

¹ See References in Text note below.

(B) the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

(3) Suspension of tolerance or exemption following suspension of associated registrations

(A) Suspension

If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) of this section shall apply to actions taken under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

(B) Effect of suspension

The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be in effect. If the suspension of use of the pesticide under that Act is terminated, leaving the registration of the pesticide for such use in effect under that Act, the Administrator shall rescind any associated suspension of tolerance or exemption.

(4) Tolerances for unavoidable residues

In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were suspended or canceled prior to August 3, 1996, under the Federal Insecticide, Fungicide, and Rodenticide Act, if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue. In establishing such a tolerance, the Administrator shall take into account both the factors set forth in subsection (b)(2) of this section and the unavoidability of the residue. Subsection (e) of this section shall apply to the establishment of such tolerance. The Administrator shall review any such tolerance periodically and modify it as necessary so that it allows no greater level of the pesticide chemical residue than is unavoidable.

(5) Pesticide residues resulting from lawful application of pesticide

Notwithstanding any other provision of this chapter, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under

this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

(A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act; and

(B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this chapter;

unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e) of this section, the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

(6) Tolerance for use of pesticides under an emergency exemption

If the Administrator grants an exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136p) for a pesticide chemical, the Administrator shall establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue. Such a tolerance or exemption from a tolerance shall have an expiration date. The Administrator may establish such a tolerance or exemption without providing notice or a period for comment on the tolerance or exemption. The Administrator shall promulgate regulations within 365 days after August 3, 1996, governing the establishment of tolerances and exemptions under this paragraph. Such regulations shall be consistent with the safety standard under subsections (b)(2) and (c)(2) of this section and with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

(m) Fees

(1) Amount

The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. Under the regulations, the performance of the Administrator's services or other functions under this section, including—

(A) the acceptance for filing of a petition submitted under subsection (d) of this section;

(B) establishing, modifying, leaving in effect, or revoking a tolerance or establishing, modifying, leaving in effect, or revoking an exemption from the requirement for a tolerance under this section;

(C) the acceptance for filing of objections under subsection (g) of this section; or

(D) the certification and filing in court of a transcript of the proceedings and the record under subsection (h) of this section;

may be conditioned upon the payment of such fees. The regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purposes of this subsection.

(2) Deposit

All fees collected under paragraph (1) shall be deposited in the Reregistration and Expedited Processing Fund created by section 4(k) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a-1(k)]. Such fees shall be available to the Administrator, without fiscal year limitation, for the performance of the Administrator's services or functions as specified in paragraph (1).

(3) Prohibition

During the period beginning on October 1, 2007, and ending on September 30, 2012, the Administrator shall not collect any tolerance fees under paragraph (1).

(n) National uniformity of tolerances

(1) "Qualifying pesticide chemical residue" defined

For purposes of this subsection, the term "qualifying pesticide chemical residue" means a pesticide chemical residue resulting from the use, in production, processing, or storage of a food, of a pesticide chemical that is an active ingredient and that—

(A) was first approved for such use in a registration of a pesticide issued under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a(c)(5)] on or after April 25, 1985, on the basis of data determined by the Administrator to meet all applicable requirements for data prescribed by regulations in effect under that Act [7 U.S.C. 136 et seq.] on April 25, 1985; or

(B) was approved for such use in a reregistration eligibility determination issued under section 4(g) of that Act [7 U.S.C. 136a-1(g)] on or after August 3, 1996.

(2) "Qualifying Federal determination" defined

For purposes of this subsection, the term "qualifying Federal determination" means a tolerance or exemption from the requirement for a tolerance for a qualifying pesticide chemical residue that—

(A) is issued under this section after August 3, 1996, and determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption) of this section; or

(B)(i) pursuant to subsection (j) of this section is remaining in effect or is deemed to have been issued under this section, or is regarded under subsection (k) of this section as exempt from the requirement for a tolerance; and

(ii) is determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption) of this section.

(3) Limitation

The Administrator may make the determination described in paragraph (2)(B)(ii) only

by issuing a rule in accordance with the procedure set forth in subsection (d) or (e) of this section and only if the Administrator issues a proposed rule and allows a period of not less than 30 days for comment on the proposed rule. Any such rule shall be reviewable in accordance with subsections (g) and (h) of this section.

(4) State authority

Except as provided in paragraphs (5), (6), and (8) no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residue in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination. A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on a food if it purports to prohibit or penalize the production, processing, shipping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit).

(5) Petition procedure

(A) In general

Any State may petition the Administrator for authorization to establish in such State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to such qualifying pesticide chemical residue.

(B) Petition requirements

Any petition under subparagraph (A) shall—

(i) satisfy any requirements prescribed, by rule, by the Administrator; and

(ii) be supported by scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues, data on the consumption within such State of food bearing the pesticide chemical residue, and data on exposure of humans within such State to the pesticide chemical residue.

(C) Authorization

The Administrator may, by order, grant the authorization described in subparagraph (A) if the Administrator determines that the proposed State regulatory limit—

(i) is justified by compelling local conditions; and

(ii) would not cause any food to be a violation of Federal law.

(D) Treatment

In lieu of any action authorized under subparagraph (C), the Administrator may treat a petition under this paragraph as a petition under subsection (d) of this section to modify or revoke a tolerance or an exemption. If the Administrator determines to treat a petition under this paragraph as a petition under subsection (d) of this section, the Administrator shall thereafter act on the peti-

tion pursuant to subsection (d) of this section.

(E) Review

Any order of the Administrator granting or denying the authorization described in subparagraph (A) shall be subject to review in the manner described in subsections (g) and (h) of this section.

(6) Urgent petition procedure

Any State petition to the Administrator pursuant to paragraph (5) that demonstrates that consumption of a food containing such pesticide residue level during the period of the food's likely availability in the State will pose a significant public health threat from acute exposure shall be considered an urgent petition. If an order by the Administrator to grant or deny the requested authorization in an urgent petition is not made within 30 days of receipt of the petition, the petitioning State may establish and enforce a temporary regulatory limit on a qualifying pesticide chemical residue in or on the food. The temporary regulatory limit shall be validated or terminated by the Administrator's final order on the petition.

(7) Residues from lawful application

No State or political subdivision may enforce any regulatory limit on the level of a pesticide chemical residue that may appear in or on any food if, at the time of the application of the pesticide that resulted in such residue, the sale of such food with such residue level was lawful under this section and under the law of such State, unless the State demonstrates that consumption of the food containing such pesticide residue level during the period of the food's likely availability in the State will pose an unreasonable dietary risk to the health of persons within such State.

(8) Savings

Nothing in this chapter preempts the authority of any State or political subdivision to require that a food containing a pesticide chemical residue bear or be the subject of a warning or other statement relating to the presence of the pesticide chemical residue in or on such food.

(o) Consumer right to know

Not later than 2 years after August 3, 1996, and annually thereafter, the Administrator shall, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, publish in a format understandable to a lay person, and distribute to large retail grocers for public display (in a manner determined by the grocer), the following information, at a minimum:

(1) A discussion of the risks and benefits of pesticide chemical residues in or on food purchased by consumers.

(2) A listing of actions taken under subparagraph (B) of subsection (b)(2) of this section that may result in pesticide chemical residues in or on food that present a yearly or lifetime risk above the risk allowed under subparagraph (A) of such subsection, and the food on which the pesticide chemicals producing the residues are used.

(3) Recommendations to consumers for reducing dietary exposure to pesticide chemical residues in a manner consistent with maintaining a healthy diet, including a list of food that may reasonably substitute for food listed under paragraph (2).

Nothing in this subsection shall prevent retail grocers from providing additional information.

(p) Estrogenic substances screening program

(1) Development

Not later than 2 years after August 3, 1996, the Administrator shall in consultation with the Secretary of Health and Human Services develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.

(2) Implementation

Not later than 3 years after August 3, 1996, after obtaining public comment and review of the screening program described in paragraph (1) by the scientific advisory panel established under section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136w(d)] or the science advisory board established by section 4365² of title 42, the Administrator shall implement the program.

(3) Substances

In carrying out the screening program described in paragraph (1), the Administrator—

(A) shall provide for the testing of all pesticide chemicals; and

(B) may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such substance.

(4) Exemption

Notwithstanding paragraph (3), the Administrator may, by order, exempt from the requirements of this section a biologic substance or other substance if the Administrator determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen.

(5) Collection of information

(A) In general

The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program described in paragraph (1), and submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

²See References in Text note below.

(B) Procedures

To the extent practicable the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information.

(C) Failure of registrants to submit information**(i) Suspension**

If a registrant of a substance referred to in paragraph (3)(A) fails to comply with an order under subparagraph (A) of this paragraph, the Administrator shall issue a notice of intent to suspend the sale or distribution of the substance by the registrant. Any suspension proposed under this paragraph shall become final at the end of the 30-day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period a person adversely affected by the notice requests a hearing or the Administrator determines that the registrant has complied fully with this paragraph.

(ii) Hearing

If a person requests a hearing under clause (i), the hearing shall be conducted in accordance with section 554 of title 5. The only matter for resolution at the hearing shall be whether the registrant has failed to comply with an order under subparagraph (A) of this paragraph. A decision by the Administrator after completion of a hearing shall be considered to be a final agency action.

(iii) Termination of suspensions

The Administrator shall terminate a suspension under this subparagraph issued with respect to a registrant if the Administrator determines that the registrant has complied fully with this paragraph.

(D) Noncompliance by other persons

Any person (other than a registrant) who fails to comply with an order under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under section 16 of the Toxic Substances Control Act [15 U.S.C. 2615] in the case of a violation referred to in that section. Such penalties and sanctions shall be assessed and imposed in the same manner as provided in such section 16.

(6) Agency action

In the case of any substance that is found, as a result of testing and evaluation under this section, to have an endocrine effect on humans, the Administrator shall, as appropriate, take action under such statutory authority as is available to the Administrator, including consideration under other sections of this chapter, as is necessary to ensure the protection of public health.

(7) Report to Congress

Not later than 4 years after August 3, 1996, the Administrator shall prepare and submit to Congress a report containing—

(A) the findings of the Administrator resulting from the screening program described in paragraph (1);

(B) recommendations for further testing needed to evaluate the impact on human health of the substances tested under the screening program; and

(C) recommendations for any further actions (including any action described in paragraph (6)) that the Administrator determines are appropriate based on the findings.

(q) Schedule for review**(1) In general**

The Administrator shall review tolerances and exemptions for pesticide chemical residues in effect on the day before August 3, 1996, as expeditiously as practicable, assuring that—

(A) 33 percent of such tolerances and exemptions are reviewed within 3 years of August 3, 1996;

(B) 66 percent of such tolerances and exemptions are reviewed within 6 years of August 3, 1996; and

(C) 100 percent of such tolerances and exemptions are reviewed within 10 years of August 3, 1996.

In conducting a review of a tolerance or exemption, the Administrator shall determine whether the tolerance or exemption meets the requirements of subsections³ (b)(2) or (c)(2) of this section and shall, by the deadline for the review of the tolerance or exemption, issue a regulation under subsection (d)(4) or (e)(1) of this section to modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.

(2) Priorities

In determining priorities for reviewing tolerances and exemptions under paragraph (1), the Administrator shall give priority to the review of the tolerances or exemptions that appear to pose the greatest risk to public health.

(3) Publication of schedule

Not later than 12 months after August 3, 1996, the Administrator shall publish a schedule for review of tolerances and exemptions established prior to August 3, 1996. The determination of priorities for the review of tolerances and exemptions pursuant to this subsection is not a rulemaking and shall not be subject to judicial review, except that failure to take final action pursuant to the schedule established by this paragraph shall be subject to judicial review.

(r) Temporary tolerance or exemption

The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.] or upon the Administrator's

³So in original. Probably should be "subsection".

own initiative, establish a temporary tolerance or exemption for the pesticide chemical residue for the uses covered by the permit. Subsections (b)(2), (c)(2), (d), and (e) of this section shall apply to actions taken under this subsection.

(s) Savings clause

Nothing in this section shall be construed to amend or modify the provisions of the Toxic Substances Control Act [15 U.S.C. 2601 et seq.] or the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.].

(June 25, 1938, ch. 675, § 408, as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; amended Pub. L. 85-791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91-515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92-157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92-516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98-620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102-300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102-571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103-80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104-170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1514; Pub. L. 105-324, § 2(b), Oct. 30, 1998, 112 Stat. 3036; Pub. L. 110-94, § 4(d)(2), Oct. 9, 2007, 121 Stat. 1002.)

REFERENCES IN TEXT

The Federal Rules of Civil Procedure, referred to in subsec. (g)(2)(B), are set out in the Appendix to Title 28, Judiciary and Judicial Procedure.

Section 346 of this title, referred to in subsec. (j)(1), originally consisted of subsecs. (a) and (b). Subsec. (a) was redesignated as the entire section 346 and subsec. (b) was repealed by Pub. L. 86-618, title I, § 103(a)(1), 74 Stat. 398.

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsecs. (l), (n)(1)(A), (r), and (s), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92-516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (§ 136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

Section 4365 of title 42, referred to in subsec. (p)(2), was in the original “section 8 of the Environmental Research, Development, and Demonstration Act of 1978”, and was translated as meaning section 8 of the Environmental Research, Development, and Demonstration Authorization Act of 1978, to reflect the probable intent of Congress.

The Toxic Substances Control Act, referred to in subsec. (s), is Pub. L. 94-469, Oct. 11, 1976, 90 Stat. 2003, as amended, which is classified generally to chapter 53 (§ 2601 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 2601 of Title 15 and Tables.

CODIFICATION

August 3, 1996, referred to in subsecs. (k), (n)(1)(B), (2)(A), and (p)(1), (2), (7), was in the original references to the date of enactment of this subsection and the date of enactment of this section, which was translated as meaning the date of enactment of Pub. L. 104-170, which amended this section generally, to reflect the probable intent of Congress.

AMENDMENTS

2007—Subsec. (m)(3). Pub. L. 110-94 added par. (3).

1998—Subsec. (j)(4). Pub. L. 105-324 added par. (4).

1996—Pub. L. 104-170 amended section generally, substituting, in subsec. (a), provisions relating to requirement for tolerance or exemption for provisions relating to conditions for safety; in subsec. (b), provisions relat-

ing to authority and standard for tolerance for provisions relating to establishment of tolerances; in subsec. (c), provisions relating to authority and standard for exemptions for provisions relating to exemptions; in subsec. (d), provisions relating to petition for tolerance or exemption for provisions relating to regulations pursuant to petition, publication of notice, time for issuance, referral to advisory committees, effective date, and hearings; in subsec. (e), provisions relating to action on Administrator's own initiative for provisions relating to regulations pursuant to Administrator's proposals; in subsec. (f), provisions relating to special data requirements for provisions relating to data submitted as confidential; in subsec. (g), provisions relating to effective date, objections, hearings, and administrative review for provisions relating to advisory committees and their appointment, composition, compensation, and clerical assistance; in subsec. (h), provisions relating to judicial review for provisions relating to right of consultation; in subsec. (i), provisions relating to confidentiality and use of data for provisions relating to judicial review; in subsec. (j), provisions relating to status of previously issued regulations for provisions relating to temporary tolerances; in subsec. (k), provisions relating to transitions for provisions relating to regulations based on public hearings before January 1, 1953; in subsec. (l), provisions relating to harmonization with action under other laws for provisions relating to pesticides under Federal Insecticide, Fungicide, and Rodenticide Act, functions of Administrator of Environmental Protection Agency, certifications, hearings, time limitations, opinions, and regulations; in subsec. (m), provisions relating to fees for provisions relating to amendment of regulations; in subsec. (n), provisions relating to national uniformity of tolerances for provisions relating to guaranties; in subsec. (o), provisions relating to consumer right to know for provisions relating to payment of fees, services or functions conditioned on payment, and waiver or refund of fees; and adding subsecs. (p) to (s).

1993—Pub. L. 103-80, § 3(k)(6), substituted “Administrator” for “Secretary” wherever appearing except when followed by “of Agriculture”.

Subsec. (a)(1). Pub. L. 103-80, § 3(k)(1), substituted “Administrator of the Environmental Protection Agency (hereinafter in this section referred to as the ‘Administrator’)” for “Secretary of Health and Human Services”.

Subsec. (d)(5). Pub. L. 103-80, § 3(k)(2), substituted “section 556(c) of title 5” for “section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c))”.

Subsec. (l). Pub. L. 103-80, § 3(k)(3), substituted “In the event” for “It the event” before “a hearing is requested”.

Subsec. (n). Pub. L. 103-80, § 3(k)(4), made technical amendment to reference to section 333(c) of this title to reflect amendment of corresponding provision of original act.

Subsec. (o). Pub. L. 103-80, § 3(k)(5), which directed the substitution of “Administrator” for “Secretary of Health and Human Services” wherever appearing in the original text, was executed by making the substitution in the first sentence before “shall by regulation require”, the only place “Secretary of Health and Human Services” appeared in the original text.

1992—Subsecs. (a), (d), (h), (i), (l), (m), (o). Pub. L. 102-300 substituted “Health and Human Services” for “Health, Education, and Welfare” wherever appearing in the original statutory text.

Subsec. (g). Pub. L. 102-571 substituted “379e” for “376”.

1984—Subsec. (i)(5). Pub. L. 98-620 struck out provision that required the court to advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

1972—Subsecs. (d)(1), (e), (l). Pub. L. 92-516 substituted references to pesticide for references to economic poison wherever appearing therein.

1971—Subsec. (g). Pub. L. 92-157 struck out “, which the Secretary shall by rules and regulations prescribe,”

after “as compensation for their services a reasonable per diem” prior to amendment in 1970, by Pub. L. 91-515, which overlooked such language when amending subsec. (g) as provided in 1970 Amendment note.

1970—Subsec. (g). Pub. L. 91-515 substituted provisions authorizing members of an advisory committee to receive compensation and travel expenses in accordance with section 376(b)(5)(D) of this title, for provisions authorizing such members to receive as compensation a reasonable per diem for time actually spent on committee work, and necessary traveling and subsistence expenses while serving away from their places of residence.

1958—Subsec. (i)(2). Pub. L. 85-791, §20(a), in first sentence, substituted “transmitted by the clerk of the court to the Secretary, or” for “served upon the Secretary, or upon”, substituted “file in the court the record of the proceedings” for “certify and file in the court a transcript of the proceedings and the record”, and inserted “as provided in section 2112 of title 28”, and which, in second sentence, substituted “the filing of such petition” for “such filing”.

Subsec. (i)(3). Pub. L. 85-791, §20(b), in first sentence, substituted “transmitted by the clerk of the court to the Secretary of Agriculture, or” for “served upon the Secretary of Agriculture, or upon”, substituted “file in the court the record of the proceedings” for “certify and file in the court a transcript of the proceedings and the record”, and inserted “as provided in section 2112 of title 28”, and, in second sentence, substituted “the filing of such petition” for “such filing”.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 110-94 effective Oct. 1, 2007, see section 6 of Pub. L. 110-94, set out as a note under section 136a of Title 7, Agriculture.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98-620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98-620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92-516 effective at close of Oct. 21, 1972, except if regulations are necessary for implementation of any provision that becomes effective on Oct. 21, 1972, and continuation in effect of subchapter I of chapter 6 of Title 7, Agriculture, and regulations thereunder, relating to control of economic poisons, as in existence prior to Oct. 21, 1972, until superseded by provisions of Pub. L. 92-516 and regulations thereunder, see section 4 of Pub. L. 92-516, set out as an Effective Date note under section 136 of Title 7.

TOLERANCE FEES

Pub. L. 108-199, div. G, title V, §501(d)(2), Jan. 23, 2004, 118 Stat. 422, provided that: “Notwithstanding section 408(m)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(m)(1)), during the period beginning on October 1, 2003, and ending on September 30, 2008, the Administrator of the Environmental Protection Agency shall not collect any tolerance fees under that section.”

DATA COLLECTION ACTIVITIES TO ASSURE HEALTH OF INFANTS AND CHILDREN

Section 301 of Pub. L. 104-170 provided that:

“(a) IN GENERAL.—The Secretary of Agriculture, in consultation with the Administrator of the Environmental Protection Agency and the Secretary of Health and Human Services, shall coordinate the development and implementation of survey procedures to ensure that adequate data on food consumption patterns of infants and children are collected.

“(b) PROCEDURES.—To the extent practicable, the procedures referred to in subsection (a) shall include the collection of data on food consumption patterns of a statistically valid sample of infants and children.

“(c) RESIDUE DATA COLLECTION.—The Secretary of Agriculture shall ensure that the residue data collection activities conducted by the Department of Agriculture in cooperation with the Environmental Protection Agency and the Department of Health and Human Services, provide for the improved data collection of pesticide residues, including guidelines for the use of comparable analytical and standardized reporting methods, and the increased sampling of foods most likely consumed by infants and children.”

§ 346b. Authorization of appropriations

There are authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, such sums as may be necessary for the purpose and administration of sections 321(q), (r), 342(a)(2), and 346a of this title.

(July 22, 1954, ch. 559, §4, 68 Stat. 517.)

CODIFICATION

Section was not enacted as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§ 347. Intrastate sales of colored oleomargarine

(a) Law governing

Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the same manner and to the same extent to the provisions of this chapter as if it had been introduced in interstate commerce.

(b) Labeling and packaging requirements

No person shall sell, or offer for sale, colored oleomargarine or colored margarine unless—

(1) such oleomargarine or margarine is packaged,

(2) the net weight of the contents of any package sold in a retail establishment is one pound or less,

(3) there appears on the label of the package (A) the word “oleomargarine” or “margarine” in type or lettering at least as large as any other type or lettering on such label, and (B) a full and accurate statement of all the ingredients contained in such oleomargarine or margarine, and

(4) each part of the contents of the package is contained in a wrapper which bears the word “oleomargarine” or “margarine” in type or lettering not smaller than 20-point type.

The requirements of this subsection shall be in addition to and not in lieu of any of the other requirements of this chapter.

(c) Sales in public eating places

No person shall possess in a form ready for serving colored oleomargarine or colored margarine at a public eating place unless a notice that oleomargarine or margarine is served is displayed prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by the ordinary individual being served in such eating place or is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items. No person shall serve colored oleomargarine or colored margarine at a public eating place, whether or not any charge is made therefor, unless (1) each separate serving bears

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY, *et al.*,

Respondents.

**DECLARATION OF MARISA ORDONIA
IN SUPPORT OF PETITIONER'S OPENING BRIEF**

I, Marisa Ordonia, hereby declare as follows:

1. I am an attorney representing Petitioners League of United Latin American Citizens, *et al.* in this case. I am submitting this declaration to provide documents relevant to arguments in our opening brief. These documents are relevant to our argument that it would be futile to wait for a decision on our administrative objections and to our request for mandamus relief, neither of which are reviewed based on the administrative record. They are also relevant to our

arguments on the merits that are reviewed based on the administrative record.

Because these documents are not currently included in the certified administrative record, we will be filing a separate motion to complete the record as well.

2. We have been working with counsel for the United States Environmental Protection Agency and Administrator Scott Pruitt (collectively “EPA”) to complete the record in this case. Counsel agree that certain documents that were before EPA when it made the decision at issue were not included in EPA’s certified index to the administrative record. On January 18, 2018, EPA produced a supplemental index to the certified administrative record that includes most of those documents.

3. Counsel for EPA take the position that the documents provided here as Exhibits A-C are not part of the administrative record.

4. Exhibits D-F were not before EPA when it made its March 29, 2017 decision to deny the petition to ban chlorpyrifos tolerances. Exhibits D-F are provided here and cited in our brief in support of our futility and unreasonable delay mandamus arguments.

5. Attached hereto as Exhibit A is a copy of an excerpted page from Administrator Pruitt’s schedule for March 9, 2017. Administrator Pruitt’s schedule for February 2017 and March 2017 was provided by EPA to the New York Times in response to a Freedom of Information Act (“FOIA”) request. The FOIA

tracking number is EPA-HQ-2017-009347. The document is available publicly at <https://foiaonline.regulations.gov/foia/action/public/view/request?objectId=090004d28141f7e4>.

6. Attached hereto as Exhibit B are copies of documents provided by EPA to the New York Times in response to a FOIA request seeking information on EPA's decision not to ban chlorpyrifos. The documents are available publicly at <https://www.nytimes.com/interactive/2017/10/21/us/document-EPA-Chlorpyrifos-FOIA-Emails-to-NYT.html>, and referenced in the October 21, 2017, New York Times article "Why Has the E.P.A. Shifted on Toxic Chemicals? An Industry Insider Helps Call the Shots," *available at* <https://www.nytimes.com/2017/10/21/us/trump-epa-chemicals-regulations.html>.

7. Attached hereto as Exhibit C are copies of handwritten notes provided by Wendy Cleland-Hamnett, former Acting Assistant Administrator of EPA's Office of Chemical Safety and Pollution Prevention, to the New York Times regarding EPA's decision not to ban chlorpyrifos. The notes are available publicly at <https://www.nytimes.com/interactive/2017/10/21/us/document-EPA-Chlorpyrifos-FOIA-Emails-to-NYT.html>, and referenced in the October 21, 2017, New York Times article "Why Has the E.P.A. Shifted on Toxic Chemicals? An Industry Insider Helps Call the Shots," *available at* <https://www.nytimes.com/2017/10/21/us/trump-epa-chemicals-regulations.html>.

8. Attached hereto as Exhibit D is a copy of a letter, dated July 18, 2017, from U.S. Senators Udall, Cardin, Blumenthal, and Booker to Chairman Roberts and Ranking Member Stabenow on the U.S. Senate Committee on Agriculture, Nutrition & Forestry.

9. Attached hereto as Exhibit E is a copy of a letter, dated October 20, 2017, from U.S. Senators Udall, Blumenthal, and Booker to Chairman Roberts and Ranking Member Stabenow on the U.S. Senate Committee on Agriculture, Nutrition & Forestry.

10. Attached hereto as Exhibit F is a copy of a letter, dated December 18, 2017, from the EPA Acting Principal Deputy Assistant Administrator of the Office of Chemical Safety and Pollution Prevention, Charlotte Bertrand, to U.S. Senator Udall, responding to issues raised in the Senators' October 20, 2017 letter referenced above as Exhibit E.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 19th day of January 2018, in Seattle, Washington.



MARISA ORDONIA

EXHIBIT

A

March 9, 2017 Continued

Thursday

The participants with Minister Carr will be:

- Janet Annesley (Chief of Staff),
- Guillaume Julien (Communications Director),
- Christyne Tremblay, Deputy Minister, Natural Resources Canada
- Jay Khosla, Assistant Deputy Minister, Natural Resources Canada
- Consul General Sara Wilshaw (Canadian Consulate in Dallas)

11:30 AM - 12:15 PM

Meet with Lynn Good, Duke Energy -- Hilton Americas-Houston, 8th floor, Room 5. Alcove for check-in.
Topic: introductory meeting and discuss Duke Energy's policy priorities
Requestor: Lynn Good
POC:

12:00 PM - 1:00 PM

Media

1:10 PM - 1:40 PM

Dr. Daniel Yergen Chair and Founder of CERA -- 22nd floor, Room 22029

1:45 PM - 2:45 PM

Speech and Plenary Session

3:05 PM - 3:30 PM

Meet with Andrew Liveris, Dow Chemical -- Hilton Americas-Houston, 8th floor, Room 5. Alcove for check-in.

4:00 PM - 4:30 PM

travel to Houston Hobby

4:55 PM - 6:40 PM

Flight: Hobby to TUL -- Southwest

March 10, 2017

Friday

All Day

Calls, etc.

8:00 AM - 9:00 AM

Chief of Staff Meeting -- Administrator's Office

EXHIBIT

B

To: Benton, Donald[benton.donald@epa.gov]
Cc: Bangerter, Layne[bangerter.layne@epa.gov]; Davis, Patrick[davis.patrick@epa.gov]
From: Ferris, Lena
Sent: Thur 3/2/2017 8:01:50 PM
Subject: RE: Farm Bureau
Meeting with WA State Members of the American Farm Bureau Federation.docx

Don – here is the meeting summary from yesterday’s Farm Bureau Meeting. The synopsis of participant concerns is on page three so can act as a stand-a-lone document should you prefer that.

Happy to follow up on any of the issues or set up meetings for you on specific topics that you would like to know more about with the program office’s.

Lena Ferris

Special Assistant to the Agricultural Advisor

Office of the Administrator

From: Benton, Donald
Sent: Wednesday, March 01, 2017 5:02 PM
To: Ferris, Lena <Ferris.Lena@epa.gov>
Subject: Farm Bureau

Lena,

Could you please provide me with a synopsis of the concerns from the group as we went around the table.

Thanks,

Don

Senator Don Benton

Senior White House Advisor

Office of the Administrator

202.564.4711



**Meeting with WA State Members of the American Farm Bureau Federation
Wednesday March 1 2017 Al Alm Conference Room EPA Headquarters**

EPA Staff from the Office of the Administrator:

Don Benton
Layne Bangerter
Patrick Davis
Lena Ferris

WA State Farm Bureau Participants:

First Name	Middle	Last Name
Michael	Glenn	LaPlant
Aaron	G	Golladay
Bradley	William	Haberman
John	Christopher	Stuhmiller
Sarah	Louise	Howard
Melodie	Janie	Kirk
Paula		McKay
Rosella	Zehnder	Mosby
Andrea	Dale	Vincent
Jon	Cordell	Wyss
Sam		Low

Don Benton began the meeting with a series of opening remarks focused on the below themes:

- The new Administration is committed to a transparent and inclusive way of moving forward.
- The new Administration recognizes that farmers are stewards and conservationists as their livelihood is based on a healthy environment and therefore farmers and ranchers already come with an understanding and an inherent desire to protect the environment.
- The new Administration is committed to developing new relationships between EPA and the agricultural community; a relationship based on partnerships not on regulations and enforcement.
- The new Administration will be appointing many new political appointees to help implement this new relationship between EPA and the agricultural community. 10 new RA's will be appointed and thousands of other positions across the Administration.
- Our goal is to help farmers comply with the law in a way that make sense.
- Discussed the role of EPA's Farm Ranch and Rural Communities FACA Committee and opportunities for new membership in the next few months.
- Don also indicated that he has already talked to the Dairy Federation regarding issues related to the Yakima Valley nitrates and understands this is a real concern for the WA State Dairies.

Administrator Pruitt joined the group for brief remarks. His remarks focused on the following themes:

- Stressed that this is a new day, a new future, for a common sense approach to environmental protection.
- President Trump signed Executive Order for EPA to reconsider and rewrite the WOTUS regulation and Administrator Pruitt wasted no time signing a FR Notice to begin implementation of that process.
- Regulations must be regular and provide the impacted communities with certainty about how to comply so that businesses can plan for necessary changes and resources.
- Regulations need to be written based on language specifically addressed within the environmental statutes and not have the statutes interrupted to meet broader goals they were not specifically designed to meet.
- The new Administration understands the tremendous economic impact agriculture plays in our economy and is looking forward to working closely with the agricultural community.

The meeting then proceeded by allowing for each of the participants to go around the room and make an observation or raise a concern. Topics were not resolved rather it was designed as a listening session for EPA to hear the concerns of the participants.

Observations/Concerns raised by participating members of the WA State Farm Bureau:

- *“What’s Upstream”*: All the participants raised concern regarding the “What’s Upstream” campaign that was funded through a subgrant awarded through EPA’s Region 10 Office.
- *Regulatory Overreach*: Members expressed concern that farmers and ranchers need for EPA to go back to what our statutes are designed to do. Farmers are trying to feed the world and EPA is making that mission harder and harder. EPA needs to be a partner in this mission not a barrier.
- *Conflicting Science*: Outstanding issues regarding conflicts between EPA science and NRCS science.
- *CWA Section 319 Grants*: The CWA 319 program has too many requirements that many farmers don’t even consider applying for the grants any longer; which is just another example of EPA making it so difficult for farmers to want to be involved in EPA programs.
- *Matrix of Regulations*: For small land owners and farmers it is usually the wife or a member of the family that is trying to navigate through the web of regulations and with more and more complicated requirements small farmers are being pushed out of business. The vulnerability of being prosecuted isn’t worth the risk to keep farming.
- *Pesticide Availability*: The huge reduction in the number of pesticides available is a large concern. When a pesticide is taken off the market farmers need more than one alternative to choose from. Farmers are always dealing with new invasive species and need more options not less for selecting pesticides to deal with those challenges.
- *Worker Protection Standards*: Concern regarding the 100-foot exclusion zone (buffer zone) around the application equipment for the spraying of pesticides.
- *EPA/FDA Conflicts*: Concern regarding the often conflicting and confusing and mounting requirements between EPA/FDA.
- *HFC’s Phase-Out*: Concern regarding the phase-out of HFC’s and the impact on smaller farms that use cold storage warehouses and difficulties/cost impacts to transitioning to other options.
- *Dairy Industry*: Concern that EPA does not understand enough about how the dairy industry works in real life and is hoping for better partnership with EPA in the coming months.
- *Chlorpyrifos*: Need a reasonable approach to regulating this pesticide and would like the farming community to be more involved in the process.
- *Opportunities for Change*: Members were excited about the new goals of the Administration, excited to be part of the change to WOTUS and expressed optimism and joy to have opportunities to partner with an EPA that is trying to help them succeed.

ED_001225_00000035-00003

To: Dravis, Samantha[dravis.samantha@epa.gov]
Cc: Kenny, Shannon[Kenny.Shannon@epa.gov]; Kime, Robin[Kime.Robin@epa.gov]
From: Rees, Sarah
Sent: Wed 3/1/2017 12:20:57 AM
Subject: Regulatory actions - for discussion 3/1
[Regulatory actions hot list March 1 2017.docx](#)

Hi Samantha – Robin asked that I put together a short list of “hot” regulatory actions on a daily basis so that you have these for your morning meeting with Administrator Pruitt. We may not have something every day, but I’ll certainly run the traps and make sure. What I have attached is a list of items that immediately require attention over the next month – to the extent they are currently in our system. I think we will soon need a focused discussion about expanding the scope of what we track so that we can more comprehensively manage the flow of regulations.

The action that I believe needs urgent focus and attention is Chlorpyrifos as we discussed yesterday. We have to take final action on revoking the tolerance for this insecticide (basically whether to ban it or not) by March 31. I know you said a briefing is already in the works to be scheduled, but I am very concerned that we are down to the wire, so have included it and added some substantive bullets.

Ex. 5 - Deliberative Process

To:
Cc: From: Sent: Subject:

Dravis, Samantha[dravis.samantha@epa.gov]
 Minoli, Kevin[Minoli.Kevin@epa.gov]; Flynn, Mike[Flynn.Mike@epa.gov] Jackson, Ryan
 Fri 3/3/2017 12:29:19 AM
 Re: Chlorpyrifos Meeting on Friday

I don't have anything on my calendar. Wendy has ask to talk to me about it and I've been involved with the Administrator all the time. I'm expecting to meet with Wendy tomorrow.

Ryan Jackson Chief
 of Staff
 U.S. EPA
 (202) 564-6999

On Mar 2, 2017, at 7:26 PM, Dravis, Samantha <dravis.samantha@epa.gov> wrote:

The meeting wasn't set up by me, it must have been Robin on my behalf after I suggested that this was a hot topic that required attention.

Ryan and I need a briefing with the appropriate parties as soon as is possible. Thanks,

Samantha

Sent from my iPhone

On Mar 2, 2017, at 6:49 PM, Minoli, Kevin <Minoli.Kevin@epa.gov> wrote:

Hi Samantha- I wanted to reach out to you and discuss a meeting request the one of OGC's attorney's received earlier today for a meeting on chlorpyrifos tomorrow.

While we are happy to meet with you and others on that subject, there were a couple points of concern I need to raise. I realize that you may not have actually set up the invitation (a ton of meetings get set up under my name), but as the senior person in OP I felt it was appropriate to write to you.

Ex. 5 - Deliberative Process, Attorney - Client Privilege

To: From: Sent: Subject:

Dravis, Samantha[dravis.samantha@epa.gov] Minoli, Kevin

Fri 3/3/2017 1:52:35 AM

Re: Chlorpyrifos Meeting on Friday

Hi Samantha- That is nice of you to send this follow-up, but you do not need to sing Robin's praises to me -- I know she is great! I wasn't thinking of anything other than passing along word to combine the two meetings if you wanted as I didn't want to presume folks wanted me to do that. Happy to have you touch base with her instead, but please don't think I was upset at her or really anyone. Normally I would have called you rather than sent an email, but I had just heard about it at 6:00 and am out in the morning, so felt it was my only option.

I will send a note to my folks that that they will likely see a revised invite or at least that the invite was not meant to exclude folks, so unless you reschedule it so Ryan can attend they should be there at 10:00.

Hope you have a good night as well. Kevin.

Kevin S. Minoli

Acting General Counsel
Office of General Counsel

US Environmental Protection
Agency Main Office Line:
202-564-8040

On Mar 2, 2017, at 8:33 PM, Dravis, Samantha <dravis.samantha@epa.gov> wrote:

Kevin, I also just wanted to make sure to say that I really don't think Robin intended to do any harm. She has gone above and beyond to help me this week, and has made me feel welcome here.

I hate to reprimand her for something when I think she was really just trying to help on an issue that I had indicated was a time pressing topic. Please bear with us as we learn routines and appropriate processes, etc. thanks and hope you have a great evening.

Sent from my iPhone

On Mar 2, 2017, at 8:07 PM, Minoli, Kevin <Minoli.Kevin@epa.gov> wrote:

Sounds like if we simply combine the two meetings we will have Ryan and Samantha, as well as OCSPP, OP, and OGC, which would be great. I am happy to email Sharnett and Robin tonight to ask them to work together to do that if that works for you. We definitely agree you both should be briefed as soon as possible, so this would be a great result if you are ok with it.

To:

Cc: From: Sent: Subject:

Dravis, Samantha[dravis.samantha@epa.gov]
Jackson, Ryan[jackson.ryan@epa.gov]; Flynn, Mike[Flynn.Mike@epa.gov] Minoli, Kevin
Thur 3/2/2017 11:49:38 PM
Chlorpyrifos Meeting on Friday

Hi Samantha- I wanted to reach out to you and discuss a meeting request the one of OGC's attorney's received earlier today for a meeting on chlorpyrifos tomorrow. While we are happy to meet with you and others on that subject, there were a couple points of concern I need to raise. I realize that you may not have actually set up the invitation (a ton of meetings get set up under my name), but as the senior person in OP I felt it was appropriate to write to you.

From: Microsoft Outlook
Location: DCRoomARN3500/OPEI
Importance: Normal
Subject: Meeting Forward Notification: Chlorpyrifos
Start Date/Time: Fri 3/3/2017 3:00:00 PM
End Date/Time: Fri 3/3/2017 3:30:00 PM

Your meeting was forwarded

Kime, Robin has forwarded your meeting request to additional recipients.

Meeting
Chlorpyrifos

Meeting Time
Friday, 03 March 2017 10:00-10:30.

Recipients
Brown, Byron

All times listed are in the following time zone: (UTC-03:00) Eastern Time (US & Canada)

Item by Microsoft Exchange Server

From: Microsoft Outlook
Location: DCRoomARN3500/OPEI
Importance: Normal
Subject: Meeting Forward Notification: Chlorpyrifos
Start Date/Time: Fri 3/3/2017 3:00:00 PM
End Date/Time: Fri 3/3/2017 3:30:00 PM

Your meeting was forwarded

Inge, Carolyn has forwarded your meeting request to additional recipients.

~~Meeting~~

Chlorpyrifos

~~Meeting Time~~

Friday, 03 March 2017 10:00-10:30.

~~Recipients~~

Reeb, Sarah

Nickerson, William

Kime, Robin

Inge, Carolyn

DCRoomARN3500/OPEI

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

Host by Microsoft Exchange Server

From: Dravis, Samantha
Location: DCRoomARN3500/OPEI
Importance: Normal
Subject: Canceled: Chlorpyrifos - Invitees Only
Start Date/Time: Fri 3/3/2017 3:00:00 PM
End Date/Time: Fri 3/3/2017 3:30:00 PM

Contact Robin with questions 564-6587.

To: Schnare, David[schnare.david@epa.gov]; Dravis, Samantha[dravis.samantha@epa.gov];
Brown, Byron[brown.byron@epa.gov]
Cc: Flynn, Mike[Flynn.Mike@epa.gov]
From: Connors, Sandra
Sent: Tue 3/7/2017 9:16:50 PM
Subject: As requested - for your further joint review and discussion: Compiled List of
Briefings/Background Papers
[Priority Briefings.docx](#)
[Priority Background Papers.docx](#)

Sandra

Sandra L. Connors
Senior Advisor

Office of the Administrator
US Environmental Protection Agency
1200 Pennsylvania Avenue, Room 3317
Washington, DC 20460
(202)564-4231

connors.sandra@epa.gov

From: Dravis, Samantha
Sent: Tuesday, March 07, 2017 8:38 PM
To: Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Cc: Kenny, Shannon <Kenny.Shannon@epa.gov>; McGartland, Al <McGartland.Al@epa.gov>
Subject: Re: Chlorpyrifos Options

Wendy, I'm not sure where things left off on getting on the Administrator's calendar. Can I help move that forward? Did you get that sorted out? Thanks for the briefing.

Sent from my iPhone

On Mar 7, 2017, at 8:31 PM, Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov> wrote:

We're still working on a short overall briefing which provides some background to this, and for which this would be the last slide. But here's what we've developed with OGC on options. We would talk about impacts of different options in the briefing.

Ex. 5 - Deliberative Process

To: Dravis, Samantha [dravis.samantha@epa.gov]
From: Benton, Donald
Sent: Wed 3/8/2017 2:34:47 PM
Subject: Re: Checking in

Weird, I was responding to your email about the 3pm. We meet everyday to boil down all the hot issues into what is most important for Scott to get decisions from him the next morning at the 8am. Love to have you instead of Shannon. She was asked yesterday to prepare a chronological list of issues based on deadline dates due to bring to each meeting. See you at 3 today.
 Don

Sent from my iPad

> On Mar 8, 2017, at 9:22 AM, Dravis, Samantha <dravis.samantha@epa.gov> wrote:

>

> I didn't get a message here.

>

> -----Original Message-----

> From: Benton, Donald

> Sent: Wednesday, March 8, 2017 8:02 AM

> To: Dravis, Samantha <dravis.samantha@epa.gov>

> Subject: Re: Checking in

>

>

>

> Sent from my iPad

>

>> On Mar 8, 2017, at 6:55 AM, Dravis, Samantha <dravis.samantha@epa.gov> wrote:

>>

>> Good morning gentlemen!

>>

>> I'm not sure what the 3pm meeting Shannon is referring to is, but from now on I would like to attend that going forward instead of Shannon. Could you forward me calendar invitations?

>>

>> Thank you!

>>

>> -----Original Message-----

>> From: Kenny, Shannon

>> Sent: Tuesday, March 7, 2017 5:40 PM

>> To: Dravis, Samantha <dravis.samantha@epa.gov>

>> Cc: Rees, Sarah <rees.sarah@epa.gov>

>> Subject: Checking in

>>

Ex. 5 - Deliberative Process

>> I attended the 3:00 daily meeting with David and Don today. We may want to talk more about that process and how to make it serve the Administrator better. It may also be good to chat about how to make it serve you better in your AA role.

To: Jackson, Ryan[jackson.ryan@epa.gov]
Cc: Brown, Byron[brown.byron@epa.gov]
From: Dravis, Samantha
Sent: Wed 3/8/2017 6:38:53 PM
Subject: Reg Reform Officer and Task Force - Approval Needed
[Summary of Regulatory EOs.docx](#)
[Interim guidance on Reducing Regulations EO - Final Version 2-2-17.docx](#)
[EO 13777.pdf](#)
[EO 13771.pdf](#)
[Presidential Memorandum Streamlining Permitting and Reducing Regulatory Burdens for Domestic Manufacturing.docx](#)

Ryan,

Per our discussion over the past few days, the Executive Order on *Enforcing the Regulatory Reform Agenda* requires EPA to implement and enforce regulatory reform and alleviate unnecessary regulatory burdens.

As part of this Executive Order, EPA needs to designate an agency official as its Regulatory Reform Officer. In past administrations, this person has typically been the OP director. We will also need to establish a "Regulatory Reform Task Force." Below are my suggestions for what we should send over to OMB, notifying them of these designations. Nothing else is required. On your green light, we will email OMB with the following.

Regulatory Reform Officer: Samantha Dravis

Regulatory Reform Task Force (subject to changes after new political appointees join):

- [REDACTED] Byron Brown
- [REDACTED] Brittany Bolen
- [REDACTED] Samantha Dravis
- [REDACTED] Ryan Jackson (Chairman) (you could change this if you like)

To: Benton, Donald[benton.donald@epa.gov]; Schnare, David[schnare.david@epa.gov]
From: Dravis, Samantha
Sent: Wed 3/8/2017 11:55:32 AM
Subject: FW: Checking in

Good morning gentlemen!

I'm not sure what the 3pm meeting Shannon is referring to is, but from now on I would like to attend that going forward instead of Shannon. Could you forward me calendar invitations?

Thank you!

-----Original Message-----

From: Kenny, Shannon
Sent: Tuesday, March 7, 2017 5:40 PM
To: Dravis, Samantha <dravis.samantha@epa.gov>
Cc: Rees, Sarah <rees.sarah@epa.gov>
Subject: Checking in

To: Dravis, Samantha[dravis.samantha@epa.gov]; Brown, Byron[brown.byron@epa.gov]
Cc: Kenny, Shannon[Kenny.Shannon@epa.gov]; Kime, Robin[Kime.Robin@epa.gov]
From: Rees, Sarah
Sent: Mon 3/6/2017 11:36:44 PM
Subject: Regulatory actions for discussion - 3/7

Hi Samantha – our “hot” regulatory items to discuss tomorrow are those we discussed at our 4pm – namely Chlorpyrifos and decision making regarding extension of the effective data for the Risk Management Plan rule, which is currently slated to become effective 3/21 if we take no further action.

Ex. 5 - Deliberative Process

To: Dravis, Samantha[dravis.samantha@epa.gov]
From: Jackson, Ryan
Sent: Wed 3/8/2017 2:11:56 AM
Subject: Re: Chlorpyrifos - Administrator Briefing

I'm kidding. Wendy is actually very helpful. I think I did scare them or surprise them Friday. They are getting us information from Friday but they know where this is headed and they are documenting it well.

Ryan Jackson
Chief of Staff
U.S. EPA
(202) 564-6999

On Mar 7, 2017, at 8:58 PM, Jackson, Ryan <jackson.ryan@epa.gov> wrote:

They are trying to strong arm us. I scared them Friday.

Ryan Jackson
Chief of Staff
U.S. EPA
(202) 564-6999

On Mar 7, 2017, at 8:48 PM, Dravis, Samantha <dravis.samantha@epa.gov> wrote:

I don't know what she's talking about. Did Shannon tell her the administrator needs a briefing??

Sent from my iPhone

Begin forwarded message:

From: "Cleland-Hamnett, Wendy" <Cleland-Hamnett.Wendy@epa.gov>
Date: March 7, 2017 at 6:53:32 PM EST
To: "Kenny, Shannon" <Kenny.Shannon@epa.gov>, "Dravis, Samantha" <dravis.samantha@epa.gov>
Cc: "Flynn, Mike" <Flynn.Mike@epa.gov>
Subject: Chlorpyrifos - Administrator Briefing

Can you let me know status? Are we still waiting to find out, or is it not happening tomorrow?

To: From: Sent: Subject:

Dravis, Samantha[dravis.samantha@epa.gov] Jackson, Ryan
Wed 3/8/2017 1:58:05 AM
Re: Chlorpyrifos - Administrator Briefing

They are trying to strong arm us. I scared them Friday.

Ryan Jackson Chief
of Staff
U.S. EPA
(202) 564-6999

On Mar 7, 2017, at 8:48 PM, Dravis, Samantha <dravis.samantha@epa.gov> wrote:

I don't know what she's talking about. Did Shannon tell her the administrator needs a briefing??

Sent from my iPhone Begin

forwarded message:

From: "Cleland-Hamnett, Wendy"
Date: March 7, 2017 at 6:53:32 PM EST

<Cleland-Hamnett.Wendy@epa.gov>

"Dravis, Samantha"

Cc: "Flynn, Mike"

Subject: Chlorpyrifos - Administrator Briefing

Can you let me know status? Are we still waiting to find out, or is it not happening tomorrow?

Thanks.

Wendy Cleland-Hamnett

Acting Assistant Administrator

i.....
.....i

Sent from my iPhone

-----Original Message-----

From: Kenny, Shannon

Sent: Tuesday, March 7, 2017 5:40 PM

To: Dravis, Samantha <dravis.samantha@epa.gov>

Cc: Rees, Sarah <rees.sarah@epa.gov>

Subject: Checking in

Ex. 5 - Deliberative Process

I attended the 3:00 daily meeting with David and Don today. We may want to talk more about that process and how to make it serve the Administrator better. It may also be good to chat about how to make it serve you better in your AA role.

Shannon

To: Minoli, Kevin[Minoli.Kevin@epa.gov]
From: Brown, Byron
Sent: Thur 3/9/2017 5:54:00 PM
Subject: RE: question

Hi Kevin – the issue I wanted to chat about relates to chlorpyrifos. Ryan asked me to follow up on something that came up in a recent discussion he had with Wendy. She advised there were a

Ex. 5 - Deliberative Process

From: Brown, Byron
Sent: Thursday, March 9, 2017 11:31 AM
To: Minoli, Kevin <Minoli.Kevin@epa.gov>
Subject: question

Hi Kevin – I stopped by but you were in a meeting. Could you give me a call when you are next free? My number is 564-1456.

From: Willis, Shamett
Location: 3402 WJC-N
Importance: Normal
Subject: Discussion on Chlorpyrifos (pre-brief for the Administrator)
Start Date/Time: Thur 3/9/2017 7:00:00 PM
End Date/Time: Thur 3/9/2017 7:30:00 PM

To: Jackson, Ryan[jackson.ryan@epa.gov]; Konkus, John[konkus.john@epa.gov]
From: Brown, Byron
Sent: Fri 3/10/2017 11:08:52 PM
Subject: Monday Agriculture Meeting
[Agricultural Leaders Meeting.docx](#)

Basic info for meeting. Purpose is to reset relationship with ag leaders

Byron R. Brown

Deputy Chief of Staff for Policy

Office of the Administrator

U.S. Environmental Protection Agency

On Mar 13, 2017, at 10:16 PM, Jackson, Ryan <jackson.ryan@epa.gov>

wrote: What's a full denial? You either do or you don't.

Ryan

Jackson

Chief of

Staff

U.S. EPA

(202) 564-6999

From: Dravis, Samantha
Sent: Thursday, March 16, 2017 10:31 AM
To: Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Cc: Jackson, Ryan <jackson.ryan@epa.gov>; Brown, Byron <brown.byron@epa.gov>
Subject: Chloropyrifos

Wendy:

I'm checking in on the draft of the petition denial for Chloropyrifos. I know we still have a bit of time before the 3/31 deadline, but I'd like to know where this is in the process as well as take a look at how the denial has been drafted given the record, to make sure we have time to ask any last minute questions. Could you send over an update?

Thank you very much.

From: Cleland-Hamnett, Wendy
Sent: Thursday, March 16, 2017 10:48 AM
To: Dravis, Samantha <dravis.samantha@epa.gov>
Cc: Jackson, Ryan <jackson.ryan@epa.gov>; Brown, Byron <brown.byron@epa.gov>
Subject: RE: Chloropyrifos

Samantha,

I received the first draft late yesterday and am now working through the 40+ pages. Will meet with OGC and the pesticides program at 11:00. Will get back to you after that.

Wendy Cleland-Hamnett

Acting Assistant Administrator

Principal Deputy Assistant Administrator

Office of Chemical Safety & Pollution Prevention

From: Dravis, Samantha
Sent: Thursday, March 16, 2017 11:04 AM
To: Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Cc: Jackson, Ryan <jackson.ryan@epa.gov>; Brown, Byron <brown.byron@epa.gov>
Subject: RE: Chloropyrifos

Great, thanks much!

To: Schwab, Justin[schwab.justin@epa.gov]; Minoli, Kevin[Minoli.Kevin@epa.gov]
Cc: Brown, Byron[brown.byron@epa.gov]
From: Dravis, Samantha
Sent: Mon 3/20/2017 2:46:17 PM
Subject: FW: Chloropyrifos
[CPYFOS.Petition Response.md.3.16.17.doc](#)

Justin and Kevin,

I have reviewed this but in case you have not, could you review the draft and submit your edits/changes to Wendy? We need to get this completed and teed up for signature by the Administrator by the end of this week in order to stay on track for a 3/31 delivery.

Thanks to you both, and happy Monday.

From: Microsoft Outlook
Location: Alm Conference Room
Importance: Normal
Subject: Meeting Forward Notification: Meeting Re: Chlorpyrifos
Start Date/Time: Fri 3/17/2017 6:00:00 PM
End Date/Time: Fri 3/17/2017 7:00:00 PM

Your meeting was forwarded

Anderson, Denise has forwarded your meeting request to additional recipients.

Meeting

Meeting Re: Chlorpyrifos

Meeting Time

Friday, March 17, 2017 2:00 PM-3:00 PM.

Recipients

Cleland-Hamnett, Wendy

Wise, Louise

Mojica, Andrea

Kelwin, Richard

Gullaran, Yu-Ting

Vogel, Dana

Lowit, Anna

Friedman, Dana

Echeverria, Marietta

McLean, Kevin

Perlis, Robert

Dwyer, Mark

Minoli, Kevin

Davis, Patrick

Schwab, Justin

Burden, Susan

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

Sent by Microsoft Exchange Server

To: Dravis, Samantha[dravis.samantha@epa.gov]
Cc: Jackson, Ryan[jackson.ryan@epa.gov]; Brown, Byron[brown.byron@epa.gov]
From: Cleland-Hamnett, Wendy
Sent: Thur 3/16/2017 6:57:21 PM
Subject: RE: Chlorpyrifos
[CPYFOS Petition Response.mtl.3.16.17.doc](#)

Samantha,

Attached is our first draft of the order denying the petition. As such, please be aware that we are still in the process of editing. If you see typos or citations, etc. to be filled in, folks are working on those. Also, it's been reviewed at the Associate General Counsel level (Kevin McLean) but Kevin Minofi and Justin Schwab haven't yet reviewed. But I think this version will allow you to see how we're describing the basis for the denial.

The most relevant sections, describing our basis for denying the petition at this time, are on pages 8-9 and 38-41. As you'll read in the notice, the Agency previously provided 2 interim responses. In 2012 we denied one claim completely and, in 2014, expressed an intent to deny 6 other claims. In this document, we're also finalizing the denial of those 6 claims to completely close out the petition response. The description of the bases for those earlier denials are cut & pasted from those earlier documents.

Ex. 5 - Deliberative Process

In the meantime, we'll also work with OPA on communications. I've asked my coms people to hold off on preparing anything until we've settled on the substance.

Always happy to answer questions or come over to discuss.

From: "McLean, Kevin" <McLean.Kevin@epa.gov>
Date: March 21, 2017 at 5:12:01 PM EDT
To: "Minoli, Kevin" <Minoli.Kevin@epa.gov>, "Schwab, Justin" <schwab.justin@epa.gov>
Cc: "Cleland-Hamnett, Wendy" <Cleland-Hamnett.Wendy@epa.gov>, "Keigwin, Richard" <Keigwin.Richard@epa.gov>, "Dyner, Mark" <dyner.mark@epa.gov>, "Perlis, Robert" <Perlis.Robert@epa.gov>
Subject: New draft chlorpyrifos petition response

Attached is the new draft of the chlorpyrifos petition response, reflecting input from OPP and DOJ, as well as additional work by Mark. (Thanks, Mark, for doing such great and quick work on this.) While some clean up remains, and Bob and I will be reviewing it as well, I think it's ready for you to look at.

Wendy—Were you able to connect with Samantha about the timing for how this should proceed, e.g., when does the finished product need to get to OP for signature by the Administrator?

Kevin and Justin—As I'm not sure what the date is for having a final package I'm not sure what to tell you in terms of review time for a precise date, so I'm afraid I just need to ask

that you review and send comments back to Mark, Bob and me as soon as possible.

The other Kevin

Thu Mar 23 09:22:18 EDT 2017
Hope.Brian@epamail.epa.gov
FW: Farmers need Chlorpyrifos
To: CMS.OEX@epamail.epa.gov

Daily Reading File

From: Ex. 6 - Personal Privacy mailto: Ex. 6 - Personal Privacy
Sent: Thursday, March 23, 2017 2:23 AM
To: Pruitt, Scott <Pruitt.Scott@epa.gov>
Subject: Farmers need Chlorpyrifos

Dear Administrator for the U.S. EPA Scott Pruitt,

The news that EPA plans to move forward with the Chlorpyrifos Tolerance Revocation process is disappointing. As a Minnesota soybean farmer, there are fewer and fewer options for us to control soybean aphids and spider mites, two of the major pests threatening soybean yields in the state.

A major outbreak of soybean aphids can cut down my yield by 40 percent. A major outbreak of spider mites could do even more damage to soybean yields.

We used to rely on Organophosphates (Chlorpyrifos), Pyrethroids and Neonicotinoids. These days, we're seeing resistance to pyrethroids in our state, namely to bifenthrin and lambda-cyhalothrin. Additionally, neonicotinoids are also under attack in Minnesota, with Gov. Mark Dayton essentially banning the use of these chemicals due to concerns with its effect on pollinators. Additionally, Sufloxafloor was denied a label for use on soybeans due to pollinator concerns.

We're losing options to combat these pests, and there are a limited number of varieties available to plant in Minnesota. Currently, the University of Minnesota is developing multiple levels of genetic resistance to be used in all maturity groups grown in the state, but it will be several years before these will be available. Furthermore, biological control using insect diseases and insect predators is inconsistent at best.

The court-ordered deadline for the decision is March 31, leaving us insufficient time to adjust for this year's growing season. If the EPA recommends revocation of the Chlorpyrifos, Minnesota farmers will be left to battle soybean aphids and spider mites with little more than a feather. I urge you to keep Chlorpyrifos in our inventory and give farmers the best chance to protect our crops.

Regards,

Ex. 6 - Personal Privacy

From: Cleland-Hamnett, Wendy
Sent: Friday, March 24, 2017 2:26 PM
To: Jackson, Ryan <jackson.ryan@epa.gov>; byron <brown@usepa.onmicrosoft.com>
Cc: Burden, Susan <Burden.Susan@epa.gov>; Mojica, Andrea <Mojica.andrea@epa.gov>
Subject: Fwd: New draft chlorpyrifos petition response

Ryan,

Here's the latest version I have. There are a few references, etc to be filled in. Clean copy ready for signature will go to OP on Monday.

Wendy Cleland-Hamnett

Acting Assistant Administrator

Principal Deputy Assistant Administrator

Office of Chemical Safety & Pollution Prevention

U.S. EPA

Begin forwarded message:

From: Hofmann, Angela
Sent: Friday, March 24, 2017 5:09 PM
To: Cleland-Hamnett, Wendy; Wise, Louise
Cc: Mojica, Andrea; Friedman, Dana; Chun, Melissa; Keigwin, Richard; Dyer, Mark; Guilaran, Yu-Ting; Smith, Charles; Costello, Kevin; Strauss, Linda; Dunton, Cheryl
Subject: Chlorpyrifos; Order Denying PANNA and NRDC's Petition to Revoke Tolerances - Electronic Copy of Final Versions

Hi Wendy,

I just dropped off the final signature package with Andrea. Attached is an electronic copy -- in case you want another look or want to share it with others.

I have things lined up with OP to get the package to them in the morning on Monday, and they are ready to process it with deadline in mind. Susan is ready to track it once I get it to OP and will coordinate getting it signed on time and back to us promptly.

- Angela

*** Deliberative Internal Document -- Do Not Cite, Quote or Release ***



UNITED STATES ENVIRONMENTAL PROTECTION
AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

**SUBJECT: Chlorpyrifos; Order Denying PANNA and NRDC's Petition to Revoke Tolerances
- ACTION MEMORANDUM**

FROM: Wendy Cleland-Hamnett
Acting Assistant Administrator (7101M)

THRU: Office of Policy (1804A)
Office of Executive Secretariat (1105A)

TO: E. Scott Pruitt
EPA Administrator (1101A)

Ex. 5 - Deliberative Process

From: Dravis, Samantha

Sent: Sunday, March 26, 2017 5:21:14 PM

To: Rees, Sarah

Subject: FW: Chlorpyrifos; Order Denying PANNA and NRDC's Petition to Revoke Tolerances - Electronic Copy of Final Versions

Let's have OEX tee this up for SPs signature.

No autopen, I need to check with the White House on this because they may want to do something in conjunction with USDA on it and I don't want it executed before I have a chance to do that.
Thanks!

From: Cleland-Hamnett, Wendy
Sent: Friday, March 24, 2017 5:45 PM
To: Jackson, Ryan <jackson.ryan@epa.gov>; Dravis, Samantha <dravis.samantha@epa.gov>; Brown, Byron <brown.byron@epa.gov>
Subject: Fw: Chlorpyrifos; Order Denying PANNA and NRDC's Petition to Revoke Tolerances - Electronic Copy of Final Versions

Status of the order below, and copy attached. Hope you all have a good weekend.

From: Hofmann, Angela
Sent: Friday, March 24, 2017 5:09 PM
To: Cleland-Hamnett, Wendy; Wise, Louise
Cc: Mojica, Andrea; Friedman, Dana; Chun, Melissa; Keigwin, Richard; Dyner, Mark; Guilaran, Yu-Ting; Smith, Charles; Costello, Kevin; Strauss, Linda; Dunton, Cheryl
Subject: Chlorpyrifos; Order Denying PANNA and NRDC's Petition to Revoke Tolerances - Electronic Copy of Final Versions

To: Samantha Dravis[Dravis.Samantha@epamail.epa.gov]
Cc: Brittany Bolen[Bolen.Brittany@epamail.epa.gov]; George Sugiyama[Sugiyama.George@epamail.epa.gov]; Kenny, Shannon[Kenny.Shannon@epa.gov]; Kime, Robin[Kime.Robin@epa.gov]; Pritchard, Eileen[Pritchard.Eileen@epa.gov]; Nickerson, William[Nickerson.William@epa.gov]; Corrales, Mark[Corrales.Mark@epa.gov]; Curry, Bridgid[Curry.Bridgid@epa.gov]; Owens, Nicole[Owens.Nicole@epa.gov]; Peffers, Mel[Peffer.Mel@epa.gov]
From: Sarah Rees
Sent: Tue 3/28/2017 7:59:23 PM
Subject: OP Policy Review - ORPM Office Director Approval Notification (SAN 5993 - Notice / Administrator's Signature / Review #1 / OCSP - 'Chlorpyrifos; Final Response to Petitions')

Approval for Administrator's Signature: Notice - 'Chlorpyrifos; Final Response to Petitions'

This Policy Review is ready for OP Associate Administrator Approval.

Link to Policy Review Document-> 

From: Dravis, Samantha
Sent: Wednesday, March 29, 2017 10:08 AM
To: Bowman, Liz <Bowman.Liz@epa.gov>; Konkus, John <konkus.john@epa.gov>; Freire, JP <Freire.JP@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>
Subject:

Headline is too hyperbolic, tone it down.

From: Bowman, Liz
Sent: Wednesday, March 29, 2017 3:55 PM
To: Freire, JP <Freire.JP@cpa.gov>
Cc: Dravis, Samantha <dravis.samantha@cpa.gov>; Konkus, John <konkus.john@cpa.gov>
Subject: RE: For Ray Review: Updated Release w USDA Quote
Importance: High

Updated with USDA Quote for joint release. Please let us know if you hear back from anyone reviewing. Do you think we could add "With Support from USDA, Admin..." Into the headline, to show it's a joint release? Or is that too much? I considered a sub-head, but I think the quote speaks for itself...

Ex. 5 - Deliberative Process

From: Burden, Susan

Sent: Wednesday, March 29, 2017 3:15 PM

To: Flynn, Mike <Flynn.Mike@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>; Brown, Byron <brown.byron@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Dravis, Samantha <dravis.samantha@epa.gov>; Minoli, Kevin <Minoli.Kevin@epa.gov>; Freire, JP <Freire.JP@epa.gov>

Cc: Mojica, Andrea <Mojica.andrea@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Curry, Bridgid <Curry.Bridgid@epa.gov>; Kime, Robin <Kime.Robin@epa.gov>; Owens, Nicole <Owens.Nicole@epa.gov>; Jutras, Nathaniel <Jutras.Nathaniel@epa.gov>; Mojica, Andrea <Mojica.andrea@epa.gov>; Knapp, Kristien <Knapp.Kristien@epa.gov>; Threet, Derek <Threet.Derek@epa.gov>; Fonseca, Silvina <Fonseca.Silvina@epa.gov>

Subject: Signed - Chlorpyrifos; Order Denying PANNA and NRDC's Petition to Revoke Tolerances

This afternoon, Administrator Pruitt signed an order denying PANNA and NRDC's petition to revoke tolerances for chlorpyrifos. A copy of the signature page is attached. Please let me know if you have any questions.

Thanks,

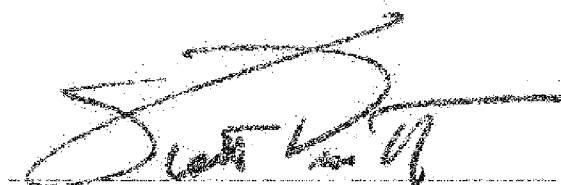
Susan

To: Dravis, Samantha[dravis.samantha@epa.gov]
Cc: Rees, Sarah[rees.sarah@epa.gov]; Owens, Nicole[Owens.Nicole@epa.gov]
From: Kime, Robin
Sent: Wed 3/29/2017 7:02:41 PM
Subject: Chlorpyrifos is signed, .pdf en route to you in a few minutes

Administrator's Signature on page 45 of 45 pages;
FRL- 9960-77: Chlorpyrifos; Order Denying PANNA and NRDC's Petition to Revoke Tolerances

Authority: 7 U.S.C. 136 *et seq.* and 21 U.S.C. 346a.

Dated: 3/29/2017



E. Scott Pruitt,

Administrator.

To: Bowman, Liz[Bowman.Liz@epa.gov]; Freire, JP[Freire.JP@epa.gov]
Cc: Konkus, John[konkus.john@epa.gov]
From: Dravis, Samantha
Sent: Wed 3/29/2017 8:01:29 PM
Subject: RE: For Ray Review: Updated Release w USDA Quote

Ray approved this

From: Bowman, Liz
Sent: Wednesday, March 29, 2017 3:55 PM
To: Freire, JP <Freire.JP@epa.gov>
Cc: Dravis, Samantha <dravis.samantha@epa.gov>; Konkus, John <konkus.john@epa.gov>
Subject: RE: For Ray Review: Updated Release w USDA Quote
Importance: High

Updated with USDA Quote for joint release. Please let us know if you hear back from anyone reviewing. Do you think we could add "With Support from USDA, Admin...." Into the headline, to show it's a joint release? Or is that too much? I considered a sub-head, but I think the quote speaks for itself...

From: Dravis, Samantha
Sent: Wednesday, March 29, 2017 4:01 PM
To: Bowman, Liz <Bowman.Liz@epa.gov>; Freire, JP <Freire.JP@epa.gov>
Cc: Konkus, John <konkus.john@epa.gov>
Subject: RE: For Ray Review: Updated Release w USDA Quote

Ray approved this

From: Bowman, Liz
Sent: Wednesday, March 29, 2017 3:55 PM
To: Freire, JP <Freire.JP@epa.gov>
Cc: Dravis, Samantha <dravis.samantha@epa.gov>; Konkus, John <konkus.john@epa.gov>
Subject: RE: For Ray Review: Updated Release w USDA Quote
Importance: High

Updated with USDA Quote for joint release. Please let us know if you hear back from anyone reviewing. Do you think we could add "With Support from USDA, Admin...." Into the headline, to show it's a joint release? Or is that too much? I considered a sub-head, but I think the quote speaks for itself...

To: Freire, JP[Freire.JP@epa.gov]; Dravis, Samantha[dravis.samantha@epa.gov]
Cc: Bowman, Liz[Bowman.Liz@epa.gov]; Wilcox, Jahan[wilcox.jahan@epa.gov]; Ferguson, Lincoln[ferguson.lincoln@epa.gov]; Bolen, Brittany[bolen.brittany@epa.gov]
From: Konkus, John
Sent: Wed 3/29/2017 2:01:50 PM
Subject: RE: For Review: Draft Press Release on Chlorpyrifos Petition

We are working on an outstanding comms plan to push this out. Really outstanding.

From: Freire, JP
Sent: Wednesday, March 29, 2017 10:00 AM
To: Dravis, Samantha <dravis.samantha@epa.gov>
Cc: Bowman, Liz <Bowman.Liz@epa.gov>; Konkus, John <konkus.john@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>; Ferguson, Lincoln <ferguson.lincoln@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>
Subject: Re: For Review: Draft Press Release on Chlorpyrifos Petition

We will pass to ray once you're through looking at it.

J.P. Freire

Environmental Protection Agency

Associate Administrator for Public Affairs

Mobile: Ex. 6 - Personal Privacy

On Mar 29, 2017, at 9:59 AM, Dravis, Samantha <dravis.samantha@epa.gov> wrote:

Did you run this by Ray Starling at the White House?

I will have some edits that I'll send shortly.

From: Bowman, Liz
Sent: Wednesday, March 29, 2017 9:46 AM
To: Dravis, Samantha <dravis.samantha@epa.gov>; Freire, JP <Freire.JP@epa.gov>; Konkus, John <konkus.john@epa.gov>; Konkus, John <konkus.john@epa.gov>
Cc: Wilcox, Jahan <wilcox.jahan@epa.gov>; Ferguson, Lincoln

Contacts: Will Rodger
(202) 406-3642
willr@fb.org

Kari Barbic
(202) 406-3672
kari@fb.org

Farm Bureau Praises EPA Chlorpyrifos Decision

WASHINGTON, D.C., March 30, 2017 – American Farm Bureau Federation President Zippy Duvall today applauded Environmental Protection Agency Administrator Scott Pruitt for rejecting a petition that would have eliminated the use of chlorpyrifos in agriculture.

"Farmers nationwide depend on chlorpyrifos in managing their crops," Duvall said. "It is widely and safely used for a wide range of crops, including alfalfa, citrus, vegetables, soybeans, almonds and others. It also protects hundreds of thousands of acres of grass seed production, where it controls aphids, cutworms and other pests. As USDA has noted, chlorpyrifos has been used as a part of environmentally friendly IPM (integrated pest management) programs for nearly 50 years."

Duvall noted that the chemical is still subject to registration review and any concerns about its safe use can be addressed in that process.

AFBF earlier filed comments with EPA expressing concern over the agency's approach. The agency had apparently relied on epidemiological studies even though researchers had failed to share raw data with the agency. EPA's own Scientific Advisory Panel, as well as USDA, had expressed caution about how the agency used the epidemiological study.

EXHIBIT C

PREPARED BY		PAGE NO.	
DATE	3/3 E/L		

PROJECT ACTION NOTES

PROJECT PLANNING NOTES

- 0 Chlorpyrifos w/ Ryan Jackson
- ⇒
- Dec needed ASAP - ask for ext - new Admin
 - Talk to Down phase out - may allow larger phase - ext pds - esp. for some uses.
 - Send draft rule to OMB?
 - Ryan - forced into a box by a petition.
 - Phase-Out alternative
 - OGC - Negotiate w/drawl of their regis (FIFRA) over a pd of time. Deny pet

~~Flu~~ VM: W @ 9:16 AM Kevin fw'g mess fr. Carolanne - Hd call fr. Sarah Rees abt Chpy - what options are being consid'd.

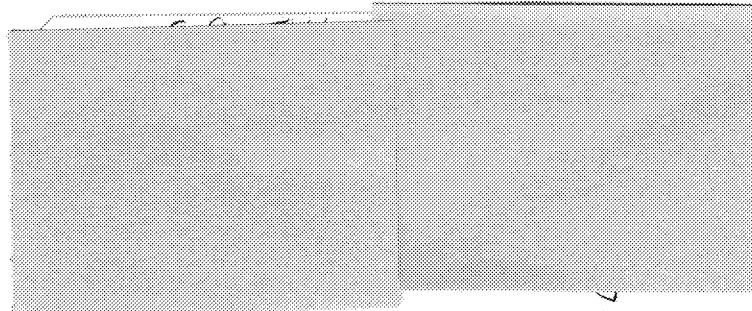
- Admin: Ryan both out.
- ✓ Back
- Wed. - Wants big paper he's asked for
- April - I Information.

PREPARED BY	
DATE	3/6

PAGE NO.	
----------	--

PROJECT ACTION NOTES

0



we only
-

0

Orig reg. new. date was 2015 - Ad say 2021 -
fr. last recd.

0 - 2015 Status Rpt. Dow may take.
DW - Intend to mitigate risk

Options

Chpy - Grant - Negot. Phase-Out
- Partial phase-out. - Deny

• Denial - legalistic argo - New admin.
diff priorities - 2022 Stat'y deadline
- Peters wot file d'ns - if they win

• Note to
Ryan J. -
Copy Minoli
i others

0

TASKS

- Papers re Hg & FW rules
- New Chems.

GOLD FIBRE®

PREPARED BY		FILE NO.
DATE	3/9/13	

PROJECT ACTION NOTES

PROJECT PLANNING NOTES

✓ Hu Ryan
draft.

- Plan to pub. 1st list of unique IDs in June (1 x yr.) draft - they're consid'g that to be June. Publ. mtg ~ 2 wks later
- ★ Hope to sign in ~ 2 wks comes to AD & Hill.

- CHPY w/ Ryan
 - 1) Bases for denial (PT - Refresh or go to end?)
 - 2) Request for extension
 - 3) USDA - Substance & Form
 - 4) Next steps.

- Debrief: Draft end of next week.
★ I'll talk to OP re OMB timing.

- OPPT GEN:
 - Scope briefings early April.

- TASKS

- ✓ ~~New chams to Corri & Chamwatch~~
- ✓ ~~Budget - fr. OMB today? Close hold~~
- ✓ ~~Hiring forms - sign & new version.~~
- ✓ ~~CHPAC WPS ltr.~~
- ✓ ~~Dates to Rebecca W.~~
- Sr Staff
 - Cong'l - PRIA #5 for CBO today
 - New Chams to Jerry today.

EXHIBIT D

United States Senate

WASHINGTON, DC 20510

July 18, 2017

The Honorable Pat Roberts
Chairman
U.S. Senate Committee on Agriculture,
Nutrition, & Forestry
328A Russell Senate Office Building
Washington, DC, 20510

The Honorable Debbie Stabenow
Ranking Member
U.S. Senate Committee on Agriculture,
Nutrition, & Forestry
328A Russell Senate Office Building
Washington, DC, 20510

Dear Chairman Roberts and Ranking Member Stabenow:

We write to express our concern about moving forward with the Pesticide Registration Information Act (PRIA) reauthorization and facilitating The Environmental Protection Agency (EPA)'s registration of pesticides without including any safeguards to ensure scientific integrity, worker protection, and EPA's compliance with its legal duty to protect the public from unreasonable harm from pesticides.

As the agency in charge of reviewing pesticides, EPA has the power to register some of the most toxic pesticides in the nation even knowing that these substances will reach our food, be washed into our water and directly contact children, farmers, farmworkers and rural communities. Unsafe pesticides can threaten the health and safety of agricultural workers when they mix and apply these chemicals, as well as when they enter fields where chemicals have been recently sprayed. They are directly consumed by children and families through produce they eat from the grocery store and can contaminate drinking water through run-off.

Since Administrator Pruitt took office, EPA has taken multiple actions in a very short time that put farmworkers, their families, rural communities -- indeed, the entire country -- at risk. Most concerning, Administrator Pruitt recently ordered that chlorpyrifos, a pesticide linked to neurodevelopmental disorders in children and acute poisonings of farm workers, can continue to be used on food, overruling the clear recommendation of EPA staff without citing any compelling contrary evidence. This decision should be reversed immediately, and we certainly cannot afford to wait five more years until October of 2022, which is the next deadline when EPA is required to re-consider this decision.

Furthermore, following requests by the agricultural industry, EPA is also proposing to delay the implementation of two rules that are vital to the protection of our nation's farmworkers: the Agricultural Worker Protection Standard (WPS) and the Certification of

Pesticide Applicators (CPA) rule. These moves are entirely inconsistent with the PRIA legislation reported by the Senate Agriculture Committee, which sets aside funds to help EPA implement these same rules that Administrator Pruitt is now seeking to delay.

Farmworkers have one of the highest rates of chemical exposures among U.S. workers. They are regularly exposed to pesticides throughout their workday in various ways, from mixing or applying pesticides to planting, weeding, harvesting or processing crops. Despite the urgent need to protect farmworkers and their families from pesticide exposure, they are afforded fewer protections than workers exposed to chemicals in other industrial sectors. While most workers look to the Department of Labor, and the Occupational Safety and Health Administration (OSHA) to protect them from dangerous chemicals, farmworkers must rely on the EPA to protect them from pesticide exposure, and thus PRIA should adequately reflect important worker safety priorities.

- **Worker Protection Standard (WPS)**

In November 2015, after more than a decade of stakeholder meetings, study and consideration, EPA finalized revisions to the WPS that provide critical improvements designed to reduce the risk of illness or injury resulting from farmworkers' occupational exposures to pesticides. The WPS calls for basic preventive measures that include: direct and timely access to pesticide application information (the use, location, and hazards of specific pesticides); the basic right to a designated representative who can access pesticide application information on a worker's behalf; a minimum age of 18 to prohibit children from applying pesticides; protection from drifting pesticides; anti-retaliation protections; and emergency assistance.

- **Certification of Pesticide Applicators (CPA)**

In January of this year, after more than 40 years, EPA updated its regulations concerning the certification of, and training requirements for, individuals who apply restricted use pesticides (RUPs), which are some of the most dangerous pesticides available on the market and are applied in agricultural, commercial and residential settings. Misuse of RUPs has resulted in injury, illness and death and highlights the importance of adequate training and proper handling of RUPs in order to protect our families from a preventable tragedy. The CPA rule enhances applicator competency standards, establishes a minimum age of 18 for pesticide applicators of RUPs, requires adequate training and supervision of non-certified pesticide applicators, and improves the quality of information that workers receive about the pesticides that they apply.

The updated WPS and CPA rules provide long-overdue protections for farmworkers, their families and rural communities across the U.S. We all have a responsibility to make sure that the families and communities most exposed to pesticides are protected.

We recognize the importance that pesticides play in the agricultural community and beyond, but must be assured of safety first. Therefore, we believe that the reauthorization of PRIA is a critical opportunity to address scientific integrity and farmworker safety, and the full Senate should include a limited number of improvements before approving this legislation, including finalizing the EPA staff recommended ban on chlorpyrifos and ensuring that the worker protection rules are implemented in a timely manner.

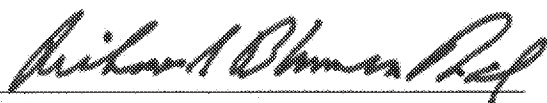
Sincerely,



Tom Udall
U.S. Senator



Benjamin L. Cardin
U.S. Senator



Richard Blumenthal
U.S. Senator



Cory A. Booker
U.S. Senator

EXHIBIT

E

United States Senate

WASHINGTON, DC 20510

October 20, 2017

The Honorable Pat Roberts
Chairman
U.S. Senate Committee on Agriculture,
Nutrition & Forestry
328A Russell Senate Office Building
Washington, DC, 20510

The Honorable Debbie Stabenow
Ranking Member
U.S. Senate Committee on Agriculture,
Nutrition & Forestry
328A Russell Senate Office Building
Washington, DC 20510

Dear Chairman Roberts and Ranking Member Stabenow:

We are following up on our letter of July 18, 2017, to provide greater clarity on the small number of reasonable actions EPA must take to ensure a minimum level of public confidence in its pesticide regulatory program before Congress should reauthorize it on a long-term basis. If the Administrator of the EPA commits in writing to the following actions, we believe that PRIA reauthorization can be expedited through the Senate on a rapid basis.

- Maintain the Agricultural Worker Protection Standard published in the federal register on November 2, 2015, including its effective dates and compliance dates, for a minimum of 3 years or the duration of PRIA reauthorization;
- Maintain the Certification of Pesticide Applicators rule published in the federal register on January 4, 2017, including its effective dates and compliance dates, for a minimum of 3 years or the duration of PRIA reauthorization; and
- Issue a final decision on the objections to the March 29, 2017 Order Denying the PAN/NRDC Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos by November 20, 2017, and on any additional objections filed regarding future chlorpyrifos decisions within 90 days of receipt.

Thank you for listening to these concerns. We stand ready to sit down and discuss these issues in further detail as soon as possible to enable passage of a long-term PRIA reauthorization with a minimum of disruption to agency operations. If the Administration fails to take such reasonable actions to restore a minimum level of confidence in its pesticide program, then we will exercise our procedural rights on the Senate floor to ensure a full debate on these issues with an opportunity for an open amendment process.

Sincerely,



Tom Udall
U.S. Senator



Richard Blumenthal
U.S. Senator



Cory A. Booker
U.S. Senator

cc:

The Honorable Scott Pruitt
The Honorable Rodney Davis

EXHIBIT

F



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 18 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

The Honorable Tom Udall
United States Senate
Washington, DC 20510

Dear Senator Udall:

This letter provides an update regarding issues raised in your October 20, 2017, letter to Senators Roberts and Stabenow. The Pesticide Registration Improvement Act provides significant benefits to the American people, expanding the availability of safe products to meet pest control needs and providing supplemental funding to support worker safety education programs.

As you know, in November 2015, the U.S Environmental Protection Agency issued an update to the Agricultural Worker Protection Standard. Through this revised regulation, developed through extensive stakeholder interactions, the agency is working with our state and tribal co-regulatory partners to implement stronger protections for agricultural workers, handlers and their families. Despite these efforts, in early 2017, the agency learned through discussions with the National Association of State Departments of Agriculture (NASDA), that additional materials to support implementation of these new protections were needed in order for the states to effectively and confidently implement the revised rule. In May 2017, the agency announced its intention to extend the compliance dates for implementation of the new rule. Upon further reconsideration, the agency has determined that it is not necessary to extend the compliance dates for the worker protection standard. On December 14, 2017, we released Federal Register Notices informing the public that the compliance dates in the revised WPS published on November 2, 2015 remain in effect and that the EPA does not intend to extend them.

The regulation issued in November 2015 remains in effect and the compliance dates of January 2, 2017 (for most aspects of the revised regulation) and January 2, 2018 (for all other aspects of the regulation) remain in place.

To better understand what support states need to implement the new standard, the EPA has been meeting with the state departments of agriculture and other stakeholders to identify which aspects of the rule might need clarification and, if necessary, revision. This conversation continued most recently as part of the November 2, 2017, meeting of the Pesticide Program Dialogue Committee (PPDC), a federal advisory committee providing advice to the Office of Pesticide Programs' policy and regulatory decisions. During the November 2017 meeting, the PPDC discussed three significant issues, also raised as part of the Regulatory Reform effort

initiated by the agency in response to Executive Orders 13771 and 13777: 1) minimum age for agricultural handlers; 2) the designated representative provision; and 3) the application exclusion zone. The following summarizes feedback the EPA received from the Regulatory Reform comments and the PPDC, as well as the agency's path forward on these targeted components of the worker protection standard:

- Regarding the minimum age provision, while PPDC stakeholders advised the agency that, for the most part, they are able to implement this provision as promulgated in the regulations, there was agreement that the "family exemption" provision was not flexible enough to accommodate family-owned and operated businesses of commercial applicators. Some stakeholders at the meeting expressed an interest in letting states determine a minimum age for agricultural handlers that meets the needs of the local rural economy. Furthermore, the EPA has heard from other stakeholders that the "family exemption" is more restrictive than USDA's definition of "family." In order to maintain current practices in rural America that allow young people to contribute to all aspects of farming operations, the EPA intends to issue a proposed rule for public comment that would reconsider the worker protection standard minimum age requirements to address these stakeholder concerns.
- Regarding the designated representative provision, the members of the PPDC noted that many states with high agricultural production have already adopted state designated representative provisions. PPDC members encouraged the EPA to consider identifying a neutral representative. A neutral representative could ensure meaningful assistance to the farm worker community and address agricultural producers concerns. At the meeting, there was not agreement on a practical way to alleviate stakeholder concerns regarding who could qualify to be a designated representative and how the information could be used, a concern also voiced via commenters on the Regulatory Reform efforts. Therefore, the agency intends to include a request in the proposed rule for public comment on reconsideration of the designated representative provision.
- Regarding the application exclusion zone ("AEZ"), the PPDC commended the agency for the additional guidance that has been issued since the promulgation of the revised rule. PPDC members did, however, identify some additional scenarios often encountered during pesticide applications where there is a need for additional guidance. The EPA is currently working on revised guidance that addresses these scenarios and hopes to issue the updated guidance by January 2, 2018. The agency will propose to make technical clarifications and codify aspects of the revised guidance related to the AEZ through the rulemaking process. These changes will provide agricultural employers and handlers certainty in practices related to applications, particularly for applications near roads and houses at the edge of a field.

In addition, the agency has been working closely with stakeholders to develop training, outreach and educational materials to ensure that the agricultural community can effectively implement the revised agricultural worker protection standard. For example, through the Pesticide Educational Resources Collaborative (PERC), a cooperative agreement between the Office of Pesticide Programs and the University of California Davis Extension, in collaboration

with Oregon State University, a large collection of materials has been developed to support implementation of the revised standard. The PERC includes an advisory board to support development of outreach, educational, and pesticide safety training materials, with membership from several state departments of agriculture, cooperative extension, and the farmworker advocacy community. More information about the PERC's activities can be found at: <http://pesticideresources.org>.

Once any necessary changes to the regulation have been made, in response to public comment, EPA will, consistent with the final rule issued on November 2, 2015, publish in the Federal Register a notice of the availability of the pesticide safety training materials for workers and handlers. To allow time for the completion and distribution of revised training materials and to allow time for trainers to become familiar with them and begin training workers and handlers, the current rule extends the implementation period for the content of the training until six months after EPA has made the revised training materials available. Nevertheless, the requirements for notification, respirator fit testing and medical evaluation, improved decontamination supplies, minimum age, and the application exclusion zone, among other provisions, do not depend upon the above-referenced Federal Register notice in order for these provisions to go into effect. These requirements went into effect on January 2, 2017, and the remaining requirements will go into effect on January 2, 2018.

Similarly, the PPDC and Regulatory Reform comments also discussed the Certification of Pesticide Applicators rule issued in January 2017. The PPDC discussed the minimum age provision in this rule and, as with the worker protection standard, identified scenarios where the "family exemption" provision was not flexible enough to accommodate for common practices in rural communities. Stakeholders commenting under the Regulatory Reform effort highlighted the increased labor costs for pesticide application businesses nationwide, and noted that the requirement was unnecessary for individuals who pass the State certification standard to apply restricted use pesticides and follow pesticide labels, including the use of personal protective equipment. Some commenters also stated that age requirements should be the decision of the States. Additionally, the minimum age provision does not provide flexibility for other common practices in rural communities, such as the hands on agricultural education young people receive via 4-H and other organizational activities. As with the worker protection standard, the agency intends to develop a proposed rule for public comment that would reconsider the certification of pesticide applicators regulation to address stakeholder's concerns.

Regarding chlorpyrifos, the March 2017 decision to deny the petition, submitted by the Natural Resources Defense Council and the Pesticide Action Network North America, initiated the objections phase of the petition process provided under the Federal Food, Drug, and Cosmetic Act (FFDCA).¹ The FFDCA requires the EPA to respond to the objections "as soon as practicable". As discussed recently with your staff, the same individuals that support the

¹ Once the EPA makes a decision on a petition, and publishes its decision in the Federal Register, the second stage of the petition process is triggered. At this point, parties who disagree with the EPA's decision, whether it is a decision to grant or deny the petition, may file objections with the EPA to the decision made. The objection stage gives parties a chance to seek review of the EPA's decision before the agency. The EPA's published response to the objections completes the objections stage, after which an adversely affected person may seek judicial review.

agency's response are also working on many other competing time-sensitive deadlines and priorities.

The statutorily mandated re-evaluation of this insecticide continues as the agency works to meet the statutory deadline for the registration review (reevaluation) of nearly 725 pesticide active ingredients by October 1, 2022. As part of the reevaluation of chlorpyrifos, EPA's scientists are also considering the comments submitted in response to the October 30, 2015, proposed rule and the November 17, 2016, notice of data availability. During these comment periods, stakeholders raised significant issues with the scientific conclusions supporting the ongoing rulemaking. We are developing responses to the comments raised in the stakeholder feedback submitted during the rulemaking process.

The EPA has several additional milestones to complete before it will be able to finalize a registration review decision for chlorpyrifos. Two of these milestones include the publication of documents with public comment periods where stakeholders can weigh in on the agency's assessments. Meanwhile, agency scientists continue to monitor and consider the ongoing research and literature evaluating the potential human health effects for chlorpyrifos. In addition, the agency also continues to consider how best to use the available observational epidemiology data in light of the comments from the FIFRA Scientific Advisory Panel as well as comments received in response to the November 2016 Notice of Data Availability. The agency estimates this work will take approximately 18 months, or 24 months if the analysis requires peer review. The Human Health Risk Assessment will then be published for a 60-day public comment period, after which the agency will prepare a response to comments document and Proposed Interim Decision, which will also be published for public comment for 60 days. The agency will then address public comments received on the Proposed Interim Decision, and develop the Interim Decision for chlorpyrifos.

Chlorpyrifos is an organophosphate pesticide, therefore, consistent with the FFDCA, the agency must update the organophosphate cumulative assessment completed in 2006. In order to revise this cumulative assessment, the agency must complete the underlying single chemical risk assessments for all of the organophosphate insecticides. Before these assessments can be completed, new studies to support physiologically based pharmacokinetic (PBPK) modeling need to be received. We anticipate receiving these studies in 2018. Once reviewed, these studies can be incorporated into the single chemical risk assessments. We anticipate seeking external peer review through the FIFRA Scientific Advisory Panel (FIFRA SAP). The purpose of the FIFRA SAP meeting will be to consider and review PBPK modeling to address pharmacokinetic differences between and within species. Based upon current resources and study submission schedules, a draft revised update to the organophosphate cumulative risk assessment will likely be issued for public comment in the late 2019-2020 timeframe.

I hope you find this information helpful as you consider a path forward for the reauthorization of PRIA. Our determination to not extend any of the compliance dates for the Worker Protection Standard is a significant change in direction. Instead, the agency will use the rulemaking process, which includes opportunity for public comment, to reconsider only a few aspects of the rule while all compliance dates continue to remain in effect.

If you have questions, please contact me or your staff may contact Sven-Erik Kaiser in the EPA's Office of Congressional and Intergovernmental Relations at kaiser.sven-erik@epa.gov or at (202) 566-2753.

Sincerely,

A handwritten signature in black ink, reading "Charlotte Bertrand". The signature is fluid and cursive, with the first name "Charlotte" and the last name "Bertrand" clearly legible.

Charlotte Bertrand
Acting Principal Deputy Assistant Administrator

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Brent Wilkes

I, BRENT WILKES, declare and state as follows:

1. I am the Chief Executive Officer of the League of United Latin American Citizens (“LULAC”). I am submitting this declaration to describe LULAC’s interests in this litigation and in obtaining a nationwide ban on chlorpyrifos.
2. As LULAC’s CEO I manage the operations of the LULAC national organization and guide the organization’s extensive legislative, public policy, and service activities in Hispanic communities throughout the United States and Puerto Rico.

3. Founded in 1929, LULAC is the country's oldest and largest Hispanic organization and our mission is to advance the economic condition, educational attainment, political influence, housing, health and civil rights of the Hispanic population of the United States.

4. With approximately 132,000 members throughout the United States and Puerto Rico, and 1,000 councils nationwide, LULAC's programs, services and advocacy address the most important issues for Latinos, meeting the critical needs of today and the future.

5. I am concerned about the health and quality of life of Latino families being exposed to toxic chemicals and pesticides. From the womb to households, workplaces and communities, Latinos are disproportionately more likely to be exposed to these neurotoxic chemicals and fighting toxic exposure to these chemicals to keep Latino communities safe and healthy is intrinsically tied to our mission.

6. The LULAC National Assembly, our organization's governing body on policy positions, has incorporated language into our platform and passed resolutions in support of fighting toxic exposure to chemicals, pesticides, and urging aggressive action by the government on this issue. On July 18, 2009, thousands of LULAC members from across the country gathered for our National convention. At this event, our membership voted for and adopted a resolution on environmental justice which among many things affirmed that Latino communities in the United States have: a right to be safe from harmful exposure; a right to prevention; a right to know what we're exposed to; a right to participate in decision making processes that have implications for our communities; and a right to protection and enforcement of policies that promote and safeguard the well-being of workers, families and communities

7. I am aware that over 2 million farmworkers, an overwhelming majority of them being Latino, and including approximately 500,000 children, are on the frontlines of exposure to pesticides in fields, nurseries, forests and greenhouses across the United States and the Commonwealth of Puerto Rico.

8. I am aware that a 2014 report on “Agricultural Pesticide Use Near Public Schools in California” assessed 2,511 public schools in the 15 California counties with the highest total reported agricultural pesticide use in 2010. At the time that the assessment was conducted, over 1.4 million students attended these schools. The report found that Hispanic children are more likely to attend schools near places that have the “highest use of pesticides of public health concern.” The six categories of pesticides of public health concern included carcinogens, reproductive and developmental toxicants, cholinesterase inhibitors, toxic air contaminants, fumigants, and priority pesticides for assessment and monitoring.

9. I am aware that exposure to pesticides increases the risk of chronic health problems among adult and child farmworkers, such as cancer, infertility, neurological disorders, and respiratory conditions. Farmworkers generally live around the fields where they work and their families are exposed to pesticides from pesticide drift and the residues taken home by their parents on their clothing.

10. When it comes to preventing children from handling pesticides, issues like personal protective equipment, the right to know about workplace chemicals, safety training and emergency assistance, are vital; yet, farmworker protection measures remain inadequate to ensure that workers are safe from the risks posed by neurotoxic chemicals like chlorpyrifos.

There are also few protections for farmworker families exposed to pesticides through drift from the fields where the pesticides are sprayed and in their drinking water.

11. On July 11, 2015, during our National Convention, LULAC members voted and approved a resolution expressing support for protecting farmworkers and their families from pesticide exposure.

12. To further environmental justice and advance protections for some of the most vulnerable segments of the Hispanic population, LULAC has been working to reduce the exposure of Latinos to toxic chemicals and pesticides.

13. I am aware that exposure to organophosphate pesticides like chlorpyrifos can lead to reduced IQ in children. This exposure threatens the health and educational attainment of Hispanic children and undermines their potential success and economic condition.

14. LULAC has submitted comments to the EPA and participated in meetings with agency officials to highlight the concerns of our membership about their families and communities. Our members live in states where chlorpyrifos is used. They work with and serve Latino communities in agricultural areas and are concerned about their exposure to this pesticide.

15. At LULAC's National Convention in the summer of 2017, we hosted a community policy briefing on the topic of chlorpyrifos. Our members heard directly from farmworker advocates and a pediatrician. LULAC members from across the country learned that children, workers, agricultural communities, and consumers are exposed to chlorpyrifos in our food, water and air, and expressed concern and urgency to engage at the federal level to ensure the EPA takes action to prohibit the continued use of this chemical.

16. In July 2017, LULAC advocates came to Washington, DC to urge their members of Congress to protect children's brains and farmworkers from pesticide poisoning by banning chlorpyrifos and supporting legislation introduced by Senator Tom Udall (D-NM) that would prohibit food uses of this chemical.

17. I am aware that EPA has a legal duty to ban the use of chemicals that it cannot deem safe for humans at any level of exposure. Yet, it has refused to do so.

18. LULAC joined this lawsuit as a petitioner because it is appalling that EPA would fail to protect some of the most exposed communities to neurotoxic chlorpyrifos when the agency's own experts cannot determine a safe level of exposure to that chemical on humans. For the hundreds of thousands of children that labor in agriculture whose brains and developing bodies are in harm's way, and farmworker families and consumers across the country, we urge the court to put a stop to the EPA's refusal to act and order the agency to ban chlorpyrifos.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 19th day of January, 2018, in Washington, D.C.



Brent Wilkes

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

DECLARATION OF AMADEO SUMANO

DECLARATION OF AMADEO SUMANO

I, AMADEO SUMANO, declare and state as follows:

1. I am over the age of 18 and have personal knowledge of the statements in this declaration.

2. This declaration is submitted in support of the lawsuit, in which United Farmworker (UFW) is a petitioner, challenging United States Environmental Protection Agency ("EPA") Administrator Scott Pruitt's decision to leave chlorpyrifos tolerances in place without finding that the pesticide is safe.

3. I am currently a member of the United Farm Workers of America and have been a member since 2014. I joined the UFW and worked at a strawberry farm because I want to raise awareness so that others would step up and help keep kids and people safe from pesticides and specifically chlorpyrifos.

4. My family and I live in Oxnard, California. My wife and I both harvest strawberries during the winter and summer harvests in Ventura County. Together we have two young boys.

5. In the summer of 2017 I was working at a strawberry farm during the land preparation before planting. My co-workers and I were instructed by the ranch supervisor to enter a section of the farm that had recently been sprayed with pesticides. As we began the work assignment my coworkers and I immediately began to smell a strong odor. Soon after my eyes and throat began to be irritated. We began to complain the danger to the supervisor but he did not reassign us and did not come out to investigate. We then called the union representative who arranged for us to be reassigned. I believe that the ranch manager was aware that the area was recently sprayed and that the reentry window had not passed.

6. This was not the only time that I felt symptoms or my body reacted to coming into contact with pesticides. Often pesticides spraying happens close to harvesting. Strawberry farm are small in comparison to other crops. Where I work the farm is approximately 100 acres. Almost every day some kind of spraying happens and of course we pick for 8 to 100 hours during the harvesting season.

7. I have worked in the strawberry industry for close to 10 years. Pesticides are a reality. Unfortunately I have realized that farm worker safety often is given less importance than the production and harvest.

8. My two sons are very young. I am afraid that they are not safe from coming into contact with pesticides like chlorpyrifos. Our community is surrounded by strawberry farms. We purposely leave our work shoes outside in the trunk of our cars to prevent contaminating our homes. But are children come into contact because after working for 8 to 10 hours, we then have to rush to the baby sitter to pick up our kids. We try to change clothes as soon as possible but it's impossible for our children to not be exposed.

9. I know that chlorpyrifos has been linked to reduced IQ, loss of working memory, developmental delays, and learning disabilities. I learned this through my work with the UFW.

10. I remain concerned about my family's exposure to pesticides generally and chlorpyrifos specifically. I know that there are residues of chlorpyrifos and other pesticides on our food even though we live in the city now. Policymakers need to address this issue and protect our children, it shouldn't always have to be on individual families. Not everyone, myself included, can feed their children organic fruits and vegetables all the time.

11. I support UFW's efforts in working to get chlorpyrifos banned. I believe that Administrator Pruitt's decision to not ban chlorpyrifos even though EPA found the pesticide to be unsafe has caused and will continue to cause harm to me and my family.

I declare under penalty of perjury that the foregoing is true and correct. Executed by me on this 18 day of January 2018 in Oxnard, California.

Armando Simone

Certificate of Translation

I declare under penalty of perjury, under the laws of the State of California, that I am fluent in written and spoken Spanish and English and that I translated and read the foregoing declaration to the declarant in a loud voice and he affirmed the contents were true and correct. Executed in Oxnard, CA 18 day of January 2018 in Oxnard, California.

Paul

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Anne Katten

I, ANNE KATTEN, declare and state as follows:

1. I am the Director of the Pesticide & Worker Safety Project at the California Rural Legal Assistance Foundation ("CRLAF"). My job responsibilities include working to bring to light and reduce agricultural work hazards and pesticide exposures faced by California's agricultural workers and other rural residents. To accomplish these goals I maintain an ongoing dialogue with Cal OSHA and local, state and federal pesticide regulatory officials to encourage more thorough investigations and stricter enforcement of existing laws and regulations, advocate for improvements in regulations, and increased use of safer and more sustainable pest control alternatives. I also provide technical assistance to attorneys from my organization, other organizations and the private bar who are providing

legal representation to farmworkers, and other workers or community members who were injured or harmed on the job or at home by pesticides or other workplace or environmental hazards. I also assist legal services programs and community organizations with developing outreach materials, accessing and understanding pesticide and work safety laws and regulations and public records and responding to pesticide poisoning incidents.

2. I submit this declaration based on my personal knowledge and based on my training and expertise as an industrial hygienist who focuses on exposures to pesticides – to farmworkers, farmworkers' families, and rural communities -- from agricultural uses. This declaration is submitted in support of the lawsuit, in which CRLAF is a plaintiff, challenging USEPA's decision to postpone action on the proposal to rescind all food tolerances for the pesticide chlorpyrifos for years.

3. I earned a Bachelor's of Science from UC Berkeley in Plant Pathology and a Masters of Public Health specializing in industrial hygiene. I joined CRLAF in 1990 as a researcher and began my current position of Pesticide and Work Safety Project Director in 1998. I have been working in my current position for 19 years, advocating to protect workers from pesticide poisoning and other workplace hazards.

4. CRLAF is a 501(c)(3) non-profit civil legal aid organization that was founded in 1981 and provides free legal services and policy advocacy for California's rural poor. CRLAF's mission is to achieve social justice and equity in partnership with farm workers and all low-wage workers and their families in rural communities through community, legislative and legal advocacy. By engaging in community education and outreach, impact litigation, legislative and administrative advocacy, and public policy leadership at the state and local level, CRLAF aims to improve working and living conditions for farm workers and other

low-wage workers.

5. CRLAF has long advocated for more comprehensive protection of agricultural workers and other rural residents from exposure to organophosphates and other pesticides which pose high acute toxicity and chronic toxicity risks.

6. Consistent with CRLAF's mission, CRLAF is deeply concerned about the double standard which has allowed continued extensive use of chlorpyrifos in agriculture over the past 15 years while in contrast residential uses were ended in 2002 due to evidence of neurodevelopmental harm to children. Allowing continued agricultural use of chlorpyrifos shows a troubling disregard for protection of the brains and intellectual potential of farmworker children.

7. California Department of Pesticide Regulation publications document that over one million pounds of chlorpyrifos are applied annually to California fields and chlorpyrifos has been found repeatedly in air monitoring conducted in agricultural regions of California as well as in household dust, urine and blood samples of pregnant women and children, surface water and food.

8. Over the past 15 years, while this double standard has been in effect the body of evidence linking even low levels of prenatal and childhood exposure to chlorpyrifos to neurodevelopmental effects including but not limited to loss of working memory, attention deficits and intelligence decrements has continued to grow as more epidemiology and animal toxicology studies are completed and published. This body of evidence includes very compelling findings from the CHAMACOS study of farmworker women and children in the Salinas Valley of California.

9. Given this overwhelming body of evidence of harm posed by exposure of pregnant woman and children to chlorpyrifos and evidence that farmworker families face the higher levels of exposure because they are in direct contact with treated plants as well as exposure through air and food, we welcomed the USEPA's proposal in 2015 to revoke all food tolerances and were extremely disappointed when EPA announced in March of 2017 that it would postpone action on this proposal for as many as five more years.

10. As part of my job, I provide technical assistance to attorneys and community outreach workers working for my own organization and other organizations that are representing fieldworkers, pesticide applicators and rural residents who have been impacted by pesticide exposure and sometimes I meet directly with these impacted individuals. I am aware of many incidents where farm workers and low-wage workers and their families have suffered acute illness which sometimes results in prolonged anxiety and disability as a result of exposure to chlorpyrifos, most commonly by drift. Between 2004-2014 the California Department of Pesticide Registration documented illness in 246 individuals to chlorpyrifos in 84 separate incidents¹. Over two thirds of these reported illnesses were due to pesticide drift and 17 percent resulted from exposure to pesticide residues. Several incidents stand out in my mind among multiple incidents of pesticide poisoning from drift of chlorpyrifos.

11. In May 2017, 37 workers in Kern County harvesting cabbage became ill after they began smelling a strong chemical odor. Tests confirmed that the pesticide had drifted a half mile from a tangerine orchard to the cabbage field.

12. In July 2007, the pesticide chlorpyrifos drifted from a walnut orchard across a road to a grape vineyard where a number of farm workers were pulling grape leaves. When

¹ http://www.cdpr.ca.gov/docs/whs/pdf/chlorpyrifos_cases_reported.pdf

the pesticide drifted, a number of workers became ill. The vineyard owner transported ten workers to the hospital for treatment, with one going home first to shower and then going to the hospital. Of these 11 farm workers, three of them had been vomiting. Later in the day, an additional 17 farm workers went to the hospital for treatment. Of these 17, two had previously been vomiting. Ten of the workers' clothes also tested positive for the pesticide. In total, 28 field workers experienced symptoms relating to chlorpyrifos exposure.

13. CRLAF is very concerned that the delay of revocation of tolerances and cancellation of food crop chlorpyrifos registrations will result in continued harm to the health and intellectual potential of California children, especially children of farm workers and other rural residents who live and go to school near to agricultural fields where chlorpyrifos continues to be used. The longer this action is delayed, the greater the number of farmworker children and other children in rural California who will be put at risk.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 17th day of January, 2018, at Sacramento, California.



Anne Katten

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Beverley Johns

I, BEVERLEY JOHNS, declare and state as follows:

1. I am the President-Elect of the Illinois chapter of Learning Disabilities Association of America (“LDAA”). I have been actively engaged with LDAA for over 30 years.

2. For 35 years, I have been a special education teacher and administrator. I worked in the public schools with children with learning disabilities and significant behavioral problems for 35 years. The vast majority of these children lived in agricultural areas where they were exposed to pesticides. I now teach at a college and consult with the public schools.

3. In 1976, my husband and I bought a home in a subdivision in Jacksonville, Illinois. Agricultural fields were right behind our home, where corn and soybeans were grown. The farmers sprayed pesticides heavily for years.

4. My husband has a rare type of blood cancer. Another man who lived two houses down from us has the same type of cancer. After my husband was diagnosed, I researched the linkage between pesticides and cancer and became concerned that the pesticide spraying at the nearby farm may have been the cause of my husband's cancer. Ever since, I have tried to minimize my and my extended family's exposure to pesticides.

5. I am also very concerned about the impact of pesticides on children. I understand that studies have found linkages between pesticides and learning and behavioral disabilities in children. In my work, I have seen the long-term effects of learning and behavioral disabilities on children and their families. Some of the students have had lifelong learning problems, have struggled with mental health problems such as depression or obsessive compulsive disorders, have struggled to keep jobs, have had a number of health problems, and unfortunately some have died early because of a variety of illnesses such as heart problems and cancer.

6. I have advised my niece and friends and other relatives to limit their children's exposures to chemicals that can cause learning disabilities. LDAA has identified specific products, such as toys with plasticizers, that should be avoided. It is much harder with food. While my niece tries to buy organic foods, others cannot afford to. And even my niece can't control what her children eat at school or their friends' houses. They also can't prevent their children from being exposed to pesticides, like chlorpyrifos, in their drinking water. The teachers I have worked with and currently work with also express concern over what their students eat and the effects of the food on their ability to learn and function.

7. It is frightening for parents to lack control over the chemicals their children encounter. Chemicals associated with learning disabilities, like chlorpyrifos, are taking their toll on our children. A lot of innocent people, and innocent children in particular, are being exposed. They and their families are suffering from the consequences of learning and behavioral disabilities that could have been avoided.

8. I am proud to be a member and elected official of LDAA because I want to work to prevent exposures to toxic chemicals that cause learning disabilities.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this _11th_ day of __January_____, 2018, in Jacksonville, Illinois.

Beverley H. Johns

BEVERLEY JOHNS

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

DECLARATION OF BONNIE WIRTZ

I, BONNIE WIRTZ, declare and state as follows:

1. I am over the age of 18 and have personal knowledge of the statements in this declaration.
2. This declaration is submitted in support of the lawsuit, in which Pesticide Action Network North America (“PAN”) is a petitioner, challenging United States Environmental Protection Agency (“EPA”) Administrator Scott Pruitt’s decision to leave chlorpyrifos tolerances in place without finding that the pesticide is safe.
3. I am currently a member of PAN and have been a member since shortly after my family and I were exposed to the pesticide chlorpyrifos in 2012. I joined PAN because I want to raise awareness so that others would step up and help keep kids and people safe from pesticides

and specifically chlorpyrifos. I have also done organizing and educational activities with a group of mom's that are concerned about our children's exposure to pesticides.

4. My family and I live in St. Paul, Minnesota. We moved back to St. Paul in January 2014. Prior to that, we lived on a farm in Melrose, Minnesota.

5. In August 2012, my family and I were exposed to chlorpyrifos when it was sprayed outside our home without warning and it came in through our air conditioning unit. I was in the room where the air conditioning unit was and the room completely filled up with the pesticide. I could not breathe and had to go to the emergency room. I almost went into cardiac arrest. My husband and my son, Jayden, were in a different room and were also exposed, but not as badly. Jayden was eight months old at the time and had skin rashes that lasted for a week. The Minnesota Department of Agriculture came out and tested for chlorpyrifos and found it on our clothing and throughout the house.

6. As he got older, we learned that Jayden had developmental delays and speech issues. He was later diagnosed with a neurodevelopmental disorder, which I believe is related to his exposure to chlorpyrifos. Jayden is now six years old and receives special education services at school.

7. We moved back to a city to be closer to treatment for my son. We also felt that it was not safe for us to do another pesticide spray season in Melrose. Our three-acre farm was surrounded by fields that sprayed a lot of pesticides, and one farm consistently sprayed chlorpyrifos. Our house was within 200 feet of that field. We had done pesticide spray drift catching with PAN and learned that we were being exposed to chlorpyrifos at four times what EPA said was safe for a one-year-old child.

8. I would love to live in the country again, but I feel that the pesticide exposure risk is too high and I am worried about the long-term impacts of continued exposure. We probably would have stayed in Melrose and farmed if not for the risk from chlorpyrifos. Our goal was to transition to a bigger farming operation over time. I have thought about moving back to the St. Cloud area, about 45 minutes from Melrose, because I had a pretty good support system of women there and I miss them. If I knew that chlorpyrifos and other pesticides were not being used, I might be more likely to move back to a rural area. I want to be farming, but I am worried about myself and my family being poisoned again.

9. I know that chlorpyrifos has been linked to reduced IQ, loss of working memory, developmental delays, and learning disabilities. I learned this through my work with PAN and from their emails, and I have done some of my own research on the impacts on children and long-term impacts on adults.

10. I remain concerned about my family's exposure to pesticides generally and chlorpyrifos specifically, especially my son. I know that there are residues of chlorpyrifos and other pesticides on our food even though we live in the city now. I have sat in the room with a lot of families with children with special needs. Many of them wonder about what is causing health problems in their children and more people are making connections to what is in the food supply. Policymakers need to address this issue and protect our children, it shouldn't always have to be on individual families. Not everyone, myself included, can feed their children organic fruits and vegetables all the time.

11. I support PAN's efforts in working to get chlorpyrifos banned. I believe that Administrator Pruitt's decision to not ban chlorpyrifos even though EPA found the pesticide to be unsafe has caused and will continue to cause harm to me and my family.

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct, to the best of my knowledge, information, and belief.

Executed this 23rd day of January, 2018, at St. Paul, Minnesota.

/s/ Bonnie Wirtz (signed with express permission)
Bonnie Wirtz

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Diana Perez

I, DIANA PEREZ, declare and state as follows:

1. I am the Washington State Director of the League of United Latin American Citizens ("LULAC"). I am also the founder of the Southwest Washington LULAC Council and a new board member of the LULAC National Education Service Center. I have been a LULAC member since 2009.

2. As a LULAC member, I have advocated for a state-level pesticide bill that would protect farmworkers and others in agricultural areas from drift. I have also taken on trying to get a ban of the pesticide chlorpyrifos in Washington state, and I have tried to get my LULAC counterparts in other states, particularly in Oregon and California, to do the same. I

communicate information about our state-level work in addressing local issues and concerns, and represent the interests of Washington Latino communities to the national LULAC organization.

3. Obtaining a statewide ban on chlorpyrifos is one of the Washington LULAC State Board's top three priorities. We set our priorities through Council input and through our community work. Washington LULAC is made up of Councils that are located in southwest Washington and in the eastern part of the state, the Tri-Cities and Yakima, which are largely agricultural areas. We have a lot of input from agricultural communities, as well as partner Latino organizations, and we are working on raising the awareness of the dangers of chlorpyrifos specifically.

4. We have a heavy agricultural landscape in Washington and a large farmworker population. I have seen and heard of a lot of abuse and exploitation of immigrant farmworkers who come here and are not aware of their rights and are not educated about the dangers of the pesticides they are exposed to, including through spray drift. I have seen how some local citizens do not get hired for these jobs because they make more of a demand for their rights. It is important to me that the people who are handling our food are treated well, healthy and aware of what they are being exposed to, and that the people who are going to consume the food are not in harm's way. I am also very concerned about the effects of pesticides, and chlorpyrifos specifically, on younger children in these communities. We have a lot of families that are exposed to pesticides through the agricultural industry. Research has shown the dangers associated with brain development.

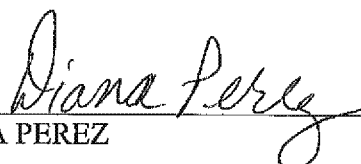
5. I am concerned about my own exposure to neurotoxic pesticides like chlorpyrifos through the food that I eat. I like to buy local food from Washington farms and businesses, but I worry about what chemicals may be on the produce. I am particularly worried about

chlorpyrifos because I know that it was banned from household use many years ago. If chlorpyrifos is not safe enough for me to clean with, then why is it on the food that I eat?

6. As a LULAC member, I want to advance the civil rights and health of our Latino population, and specifically immigrant communities. We do education programs to families and students about pesticides and neurotoxicity, but there is a huge learning curve for all of us. Our whole community, not just immigrants, are at a disadvantage in not knowing about chlorpyrifos and the risks associated with it. The data and history of chlorpyrifos show how dangerous this pesticide is and it is ridiculous that young children and families can be exposed to the long-term consequences of its use on our food.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 17 day of JAN, 2018, in Vancouver, Washington.



DIANA PEREZ

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Dr. Elena Rios

I, DR. ELENA RIOS, declare and state as follows:

1. I am the President and Chief Executive Officer of the National Hispanic Medical Association (“NHMA”). I am also the founder of NHMA, which was incorporated in 1994. I am submitting this declaration to describe NHMA’s interests in this litigation and in obtaining a nationwide ban on chlorpyrifos.

2. NHMA is a national, non-profit organization representing the interests of 50,000 Hispanic physicians and other health care professionals. NHMA’s mission is to empower Hispanic physicians and health care professionals to improve the health of Hispanic and other underserved populations. NHMA works collaboratively with Hispanic state medical societies,

medical students, residents, and other public and private sector partners. NHMA also serves as a resource, providing expert information to federal agencies, Congress, and the White House in order to strengthen public policies affecting the health of Hispanic communities across the nation.

3. As a network of concerned physicians and health care professionals, NHMA recognized early on the importance of programs and policies to protect the health of Hispanic populations and the need to lend our voices for improving the health and lives of Hispanic communities. NHMA has long advocated to improve the health and well-being of Hispanics and other underserved communities. We place a particular emphasis on protecting women and children and communities that suffer from poor health and multiple stressors.

4. We have identified reducing exposures to toxic pesticides as a priority. Many Hispanics and Hispanic communities face public health hazards from toxic pesticides used in agriculture. People employed in agriculture are directly exposed to toxic pesticides in their work. Some of our members diagnose and treat farmworkers for acute pesticide poisonings. The workers place trust in our members who speak Spanish and are aware of pesticide risks so they can effectively diagnose and treat people who are experiencing poisoning symptoms.

5. Farmworkers can bring home residues of toxic pesticides on their clothing and expose their children. Toxic pesticides also drift from the fields where they are applied to schools, homes, and other places where children live, learn, and play. Our members who are pediatricians or OB-GYN physicians and other health care providers working with children and pregnant women work to protect their patients from these hazards or reduce the harmful consequences when their patients suffer from exposures. NHMA has worked to educate its members on the risks posed by toxic pesticides and diagnosis and treatment.

6. NHMA also works on behalf of its members to address the problem at its source and reduce or eliminate these toxic exposures. NHMA has testified on Capitol Hill and submitted comments to federal agencies on the risks posed by toxic pesticides. It has submitted comments to the Environmental Protection Agency (“EPA”) and attended meetings with EPA to present scientific evidence of the harm that chlorpyrifos and other organophosphate pesticides cause to people through acute poisonings and to children from low-level exposures that cause neurodevelopmental harm. Our members have patients who suffer from autism, attention deficit disorder, and other learning disabilities that are associated with exposure to chlorpyrifos and other organophosphates. They see first-hand the damage that chemical exposure can cause and the impacts on the individual children, the families, and communities that deal with these impediments to learning.

7. At our annual conference in the spring of 2017, our young physicians chapter sponsored a session that addressed chlorpyrifos. At this session, we provided information to our members to enable them to identify the risks posed by chlorpyrifos and to be a voice for protections for their patients. At this conference, in communications with our members, and through our networks, we provide our members with information about public policy proceedings where they can submit comments or testimony. Many of our members provide information to government decision makers, drawing on their experiences with their patients or their medical backgrounds. Some of our members who are early in their medical careers raised concerns about speaking out in areas where they could face retaliation and welcome NHMA taking positions on their behalf to eliminate exposures to chlorpyrifos.

8. At a conference of the League of United Latin American Citizens in the summer of 2017, one of our members Dr. Jaime Estrada, an accomplished and Texas-based pediatrician,

participated in a panel on toxic pesticides, raising concern about the risks of chlorpyrifos to the developing brains of children and farmworker health.

9. NHMA joined this lawsuit as a petitioner because it is indefensible that EPA would expose Hispanic communities to chlorpyrifos when the evidence the harm that it causes is so overwhelming. It is particularly indefensible for EPA to allow pregnant women to be exposed to chlorpyrifos when such exposures can cause longlasting damage to their children's brains. We urge the court to put an end to EPA's delays and order EPA to ban chlorpyrifos.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 9 day of Jan., 2018, in Washington, D.C.



DR. ELENA RIOS

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Dr. Jaime Estrada

I, DR. JAIME ESTRADA, declare and state as follows:

1. I am a pediatric hematologist-oncologist. Since 1992, I have been in practice in pediatric hematology and oncology in San Antonio, Texas.
2. I graduated from the Universidad Michoacana de San Nicolas de Hidalgo in Mexico, and completed a residency in pediatrics at Cardinal Glennon Memorial Hospital in St. Louis Missouri followed by a clinical and research fellowship in pediatric hematology and oncology at the MD Anderson Hospital and Tumor Institute in Houston, Texas. I earned an MS in Biomedical Sciences with special emphasis in oncology during this fellowship. I then accepted

a position as assistant professor of pediatrics, department of hematology and oncology at the School of Medicine, University of South Florida in Tampa, Florida.

3. When I moved to San Antonio in 1992, I saw a need for medical services in pediatric hematology and oncology in south Texas including heavily agricultural areas in the Rio Grande Valley. In 1994, I started an outreach clinic in Laredo which still continues, and in 1996, I started a clinic in the Rio Grande Valley, first in Weslaco at Knapp Medical Center, and then in McAllen 2 years later. I would go and see patients at these clinics and bring them to San Antonio for diagnosis and to begin treatment when needed. At the time, I knew that these children were exposed to pesticides and wondered about the role that pesticide exposures played in the medical conditions I observed. I closed the McAllen clinic in 2005 once a local clinic opened that could provide needed medical services in pediatric hematology and oncology.

4. In the course of treating patients for cancer and blood disorders, I often see the effects of neurocognitive and psychomotor delays on children. These types of delays and impairments impact any pediatric practice, regardless of specialty. Parents often report that their children do not like to take their medications and that they are difficult to control at home and school. Poor academic progress is a frequent complaint. These are common occurrences with children experiencing hyperactivity and attention deficit disorders.

5. I have been an advocate for access to comprehensive, cost-effective health care in Texas for many years. I founded Texas Doctors for Social Responsibility in 2014 to enable doctors in Texas to come together and enhance their voices and impact on public policies affecting medical care.

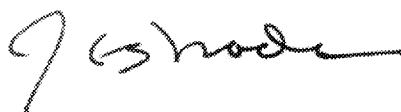
6. I have been a member of the National Hispanic Medical Association (“NHMA”) since 2004. I support NMHA’s efforts to reduce exposure to neurotoxic pesticides like chlorpyrifos.

7. In June 2017, I gave a presentation at the annual conference of League of United Latin American Citizens (“LULAC”) in San Antonio, Texas. I researched the published scientific studies on chlorpyrifos, including the Columbia study, which found a strong correlation between prenatal exposure to high levels of chlorpyrifos and subsequent cognitive and psychomotor delays. The goal of the presentation to the LULAC members was to educate them about the neurodevelopmental harm caused by this pesticide.

8. I think it needs to be a top priority to reduce or eliminate children’s exposures to chemicals like chlorpyrifos that can cause such serious long-term neuro-cognitive harm. Pregnant women who work in the fields can be exposed to levels of chlorpyrifos that can cause such harm to their children. Parents who are exposed to pesticides like chlorpyrifos when they work in the fields can bring home residues and expose their children. I strongly support NHMA’s participation in this case to protect these children and reduce the types of neuro-cognitive harms they experience from toxic exposures.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 11th day of January, 2018, in San Antonio, Texas.



DR. JAIME ESTRADA

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Erik Nicholson

I, ERIK NICHOLSON, declare and state as follows:

1. I am the National Vice President of the United Farm Workers ("UFW"). I have worked at UFW for the past fifteen years.
2. UFW is the nation's largest farm workers union. Since 1962, UFW has worked to protect and expand farm workers' rights and to protect the health of farm workers and their families, including by limiting their exposure to toxic pesticides.
3. UFW currently has more than 27,000 members. UFW members include current, seasonal, and retired farm workers.
4. UFW has a long history of advocating for better protections from dangerous pesticides. To educate farm workers, rural communities, elected officials, and the public about

the dangers of pesticide exposure, UFW prepares and disseminates papers describing the health hazards associated with certain pesticides, the inadequacies of existing protections, and the government's failure to monitor for violations or enforce rules when violations occur. UFW also advocates for legislative and regulatory reforms to protect farm workers and their families from dangerous pesticides. These efforts have achieved some success. For example, UFW established the first comprehensive health care plan for farm workers and their families. UFW also negotiated the first farm worker labor contracts with provisions to prevent pesticide exposure, such as a ban on pesticide spraying while workers are in the field, prohibitions against the use of especially dangerous pesticides, and requirements that workers have access to protective clothing, washing stations, and clean drinking water. These labor contracts also included provisions mandating medical monitoring for workers exposed to neurotoxic pesticides, including organophosphate pesticides like chlorpyrifos.

5. In my position as National Vice President, I coordinate UFW's efforts to implement national policies that provide adequate protection from dangerous pesticides and otherwise promote farm worker health and safety. I communicate with UFW's members regularly, during house visits, on farms, at membership meetings, and through social media.

6. Unlike most people, UFW's members work in an industry that intentionally introduces toxins—that is, dangerous pesticides—into the workplace. UFW has members who mix and apply pesticides to crops—including apples, pears, cherries, and peaches—and members who prune, thin, and harvest crops contaminated with pesticide residues. The workers can bring home residues of toxic pesticides like chlorpyrifos on their clothing and bodies, which then expose their family members to the pesticides. UFW has advocated for showers, workplace uniforms, and places to remove and store contaminated clothing, amongst other urgently needed

protections. While we have achieved some success, many of our members still work in places that lack such protections or facilities. Their family members continue to be at risk of hazardous exposures.

7. UFW also has members who live and work very close to areas where pesticides are applied. Sometimes the farm worker housing is located within a few feet of the fields or orchards. When pesticides are sprayed in the air, they often drift and settle on or near this farm worker housing, exposing UFW members and their families to the pesticides. Farm worker families are exposed to pesticide drift at other places they frequent, including schools, churches, hospitals, day care, and play fields. UFW has advocated for buffer zones and other restrictions on pesticide use to reduce pesticide drift. While small buffer zones are in place for chlorpyrifos, they are insufficient. For example, last year on Cinco de Mayo, chlorpyrifos drifted $\frac{1}{4}$ mile from where it was applied and poisoned workers at another farm. UFW staff immediately went to the farm to provide assistance to the sickened workers.

8. Many UFW members and their families, including children, have experienced symptoms associated with acute and chronic pesticide poisoning, including dizziness, fatigue, headache, nausea, nosebleeds, and memory loss. Some of our members suffer from long-term neurological damage or have children who have autism, attention deficit disorders, or other learning disabilities. I am aware that exposure to chlorpyrifos and organophosphates has been associated with a greater incidence of such learning disabilities. Our members face an increased risk of pesticide poisonings and their children of having learning disabilities because of their exposures to chlorpyrifos.

9. I am aware that chlorpyrifos is identified as the cause of pesticide poisoning incidents every year. Because of its widespread use and the risks it poses, UFW has made it a

priority to advocate to obtain a ban on chlorpyrifos. In 2007, we were plaintiffs in a lawsuit filed in California challenging EPA's determination to reregister chlorpyrifos. *United Farm Workers v. Administrator, EPA*, No. 07-3950. We have since participated in the registration review process along with our allies by submitting comments on EPA's risk assessments and on its 2015 proposal to ban all uses of chlorpyrifos. In 2016, we petitioned EPA again with our allies to suspend and cancel chlorpyrifos uses that pose unacceptable uses to workers. EPA identified these unacceptable risks in 2014, but continues to authorize the uses associated with them. We have met with EPA decision-makers, including the Administrator, urging the agency to act quickly to ban chlorpyrifos.

10. We have been extremely disappointed at EPA's slow pace in limiting chlorpyrifos use. More than a decade ago, EPA obtained a ban on homeowner uses that put children at risk. EPA failed to afford farm worker children comparable protection. These children were forgotten, left behind for years before EPA even acknowledged its obligation to protect them from pesticide drift.

11. We were heartened when EPA released its 2014 human health risk assessment acknowledging the extreme risks posed by chlorpyrifos to children from neurodevelopmental harm, to workers from workplace exposures, and to drinking water supplies across the country. We were also relieved when EPA proposed in 2015 to ban chlorpyrifos upon finding it unsafe and proposed to make the ban effective six months after the rule became final. At long last, our members would no longer be exposed to this dangerous pesticide on a regular basis, through multiple pathways. They would be comforted in knowing their families would not be consuming this poison in their food or drinking water, or exposed to it in the air they breathe. We believed


that 2017 would be the last year this pesticide would be sprayed on our crops, drift onto our homes, and contaminate our food and water.

12. And then in March, the new EPA Administrator did the unthinkable. He refused to ban this pesticide, not because he found it safe, but because he didn't want to act. This decision is indefensible. It puts UFW's members and their families at risk of pesticide poisonings and neurodevelopmental damage. Instead of being free of chlorpyrifos at work, at home, at school, at church, and at the dinner table last fall, UFW members and their families continue to live, work, and attend school in places where exposure to chlorpyrifos is likely. Every month that chlorpyrifos continues to be used in agriculture, UFW members and their families will be exposed to it through their work, drift and volatilization, their food, and/or their drinking water. EPA is putting UFW members at risk of acute pesticide poisonings from such exposures. It is also putting the children of UFW members at risk of damage to their brains and learning disabilities. It is unconscionable to put the families that work to help put food on our tables at risks of such egregious harm.

13. UFW has brought this lawsuit because subjecting our members to these harms has to end. UFW is also investing its resources to obtain a ban on chlorpyrifos in California. If EPA had done its job and followed the law and the science, we would not need to pursue a state ban and piecemeal protections from this dangerous pesticide.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 8th day of JANUARY, 2018, in Tacoma, Washington.


ERIK NICHOLSON

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Esteban Ortiz

I, ESTEBAN ORTIZ, declare and state as follows:

1. I am over the age of 18 and have personal knowledge of the statements in this declaration.
2. I am submitting this declaration in support of the lawsuit, in which GreenLatinos is a petitioner, challenging United States Environmental Protection Agency ("EPA") Administrator Scott Pruitt's decision to leave chlorpyrifos tolerances in place without finding that the pesticide is safe.
3. I currently live in Indianapolis, Indiana, and I have been a member of GreenLatinos since 2015. As a member of GreenLatinos, I speak with decision makers about issues that

affect the Latino community at the local level. I work as an Outreach Coordinator at the Migrant Farmworker Law Center at Indiana Legal Services, Inc. My work takes me all over the state and I speak with farmworkers about their concerns and advocate for better training and protections for them. Farmworkers and their families lack information about the pesticides used around them and the harms associated with those pesticides due to language barriers, a lack of cultural competency, and a lack of resources to provide adequate information to farmworkers.

4. I also come from a family of farmworkers and worked on a farm as a youth. Many members of my family still work on farms in Ohio and live in agricultural communities. Like the farmworkers that I serve through my job, my family members are not provided information about the pesticides that are used in their area and how they may be exposed to those pesticides. They also don't feel like they can ask questions about what pesticides are being used on the farms they work at. When I visited my mom and talked to her about the work I do advocating for farmworkers and how we explain the rights farmworkers have, she mentioned how she and her whole family never once complained about lost wages, safety trainings done in only English and not Spanish, lack of restrooms in the fields, or about pesticides. The only thing they were ever told was not to be present working in the fields when the airplanes would spray the fields with pesticides. No signs were ever posted about the time to stay off the fields. The dangers that pesticides would have on them was never explained in a language they could understand, and safety training was not required regarding any pesticides or hazards.

5. I am aware that the pesticide chlorpyrifos is used in Indiana and I fear that the farmworkers I serve may be exposed to it while at work, in and around their homes, and on their food and in their drinking water. I know that chlorpyrifos has damaging, long-term effects on people, and I support a ban on the pesticide. I am also concerned that chlorpyrifos is on the food I eat, and I am outraged that EPA refused to ban the use of this pesticide on food when they know it causes harm to people.
6. I want EPA to do its job and protect my family, as well as the farmworkers I work with and their families, by acting on the recommendations of EPA's own scientists and ban the use of chlorpyrifos on food. I support this lawsuit and GreenLatinos' ongoing efforts to get this dangerous pesticide out of our food, drinking water, and air.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 16 day of JANUARY, 2018, in Indianapolis, Indiana.



ESTEBAN ORTIZ

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Eugenia Economos

DECLARATION OF EUGENIA ECONOMOS

I, EUGENIA ECONOMOS, declare and state as follows:

1. I am the Pesticide Safety and Environmental Health Project Coordinator for the Farmworker Association of Florida ("FWAF"). The duties for my job include pesticide health and safety trainings for farmworkers; coordinating and updating such trainings and materials; training healthcare providers about diagnosing and treating cases of pesticide exposure; community-based participatory research around farmworker health and safety issues, including pesticide exposure; filing complaints for violations of certain farmworker pesticide protection regulations entrusted by the United States Environmental Protection Agency ("EPA") for

enforcement by the Florida Department of Agriculture and Consumer Services, and working for better workplace protections for farmworkers against pesticide exposures.

2. I submit this declaration based on my personal knowledge and based on my years of experience as a pesticide health and safety advocate for farmworkers and their families. This declaration is submitted in support of the lawsuit, in which FWAF is a plaintiff, challenging EPA Administrator Scott Pruitt's decision to leave chlorpyrifos tolerances in place without finding that chlorpyrifos is safe.

3. I began working with FWAF in 1995 as a volunteer and became a full-time paid employee from 1996 to 2001. For those five years, I worked on the Lake Apopka Farmworker project. The next five years, I worked in a volunteer capacity on the Lake Apopka project, before returning again as a full-time FWAF staff member in 2006. In 2007, I moved into my current position of the Health and Safety Project Coordinator. I have held my current position for over 10 years, working to educate and protect farmworkers and their families from pesticide poisoning and other workplace hazards.

4. FWAF is a grassroots, farmworker-membership, community-based organization in Florida that was founded in 1983, incorporated in 1986, expanded statewide in 1992 and that currently has over 10,000 members across the State. FWAF's long-standing mission is to build power among farmworker and rural low-income communities to respond to and gain control over the social, political, workplace, economic, health, and environmental justice issues that impact their lives. FWAF believes in the power of our membership to develop leadership in the community and generate effective action for social change. We are led and governed by the farmworker-communities in which we work. Among the many types of assistance we provide

are: disaster relief and response; pesticide health and safety training; aid to workers who have been victims of wage theft, workplace discrimination, and labor trafficking; among many others.

5. FWAF has been on the forefront of advocating for policies to protect farmworkers' health and safety, including by advocating for a chlorpyrifos ban due to the grave harms associated with that pesticide. FWAF has urged EPA to protect our members and farmworker communities from chlorpyrifos for years. We have signed onto letters calling for a ban on the pesticide, and we have submitted our own comments on EPA's various risk assessments for chlorpyrifos. In 2011, I submitted comments on behalf of FWAF that described the story of Ignacia. Ignacia came to FWAF to seek help with and possible legal recourse for her serious medical conditions that were causing her to experience a debilitating illness. She had previously seen an attorney, but he was not able to help her, because he had no experience or expertise in occupational health exposure cases. Ignacia and I talked, and she told me about her work and about being repeatedly exposed to pesticides in the workplace during the years she worked as an agricultural worker. Ignacia worked in a Florida ornamental plant nursery for over a decade and was repeatedly exposed to pesticides in her workplace, and she eventually had to quit due to her evermore concerning health problems. Ignacia sought medical help both in the U.S. and also in her home country of Mexico, where health care was more affordable and more accessible. Due to her mounting health care bills from over four years of seeking medical treatment for an increasingly worsening illness, Ignacia was afraid of losing her home in the U.S., so she came to FWAF in desperation looking for help. As the pesticide project coordinator for FWAF, it was deeply unsettling for me and emotionally gut-wrenching when all I could do was to look Ignacia in the eyes and tell her that there was nothing we could do to help her. The statute of limitations had passed for any kind of legal action. Plus, I have had enough experience

to know the obstacles and difficulties of getting any kind of legal redress for those who experience chronic health effects related to long-time exposure to pesticides. I have been haunted by this incident ever since. Because Florida does not have a pesticide use reporting requirement, I cannot obtain information about what pesticides were used and when at the nursery in question or any other nursery in our area. I know that chlorpyrifos was used in area nursery and fernery operations in Central Florida. Chlorpyrifos was probably one of the pesticides that Ignacia had been repeatedly exposed to. Lack of information about the pesticides being used in the workplace inhibited Ignacia and continues to inhibit other farmworkers in Florida from having the information they need about the pesticides that are applied in their work areas. There are many other farmworkers, like Ignacia, that suffer chronic health problems and wonder if pesticide exposure over many years of work could be one of the causes.

6. In the past, FWAF joined others in submitting comments on EPA's 2016 revised human health risk assessment for chlorpyrifos on behalf of the organization and our members. We also joined the other petitioners in filing objections with EPA following Administrator Pruitt's denial of the 2007 PAN/NRDC petition to revoke chlorpyrifos tolerances. Our objections were filed on June 5, 2017 and EPA has not provided us with a response.

7. FWAF believed that EPA would follow the law and the recommendations of its own scientists and finalize its proposed rule revoking chlorpyrifos tolerances, which we believed was a long overdue step in protecting farmworkers, their families and rural communities from exposure to this dangerous pesticide. We were pleased by what seemed to be an inevitable ban based on the growing number of studies demonstrating neurodevelopmental harm to children from chlorpyrifos, in addition to EPA's conclusion that nearly every use of chlorpyrifos posed harm to workers even with maximum protective equipment.

8. We were very disappointed when Administrator Pruitt issued the Denial of the 2007 PAN/NRDC petition on March 29, 2017. We were also surprised that EPA would leave chlorpyrifos tolerances in place after finding that it was unsafe in a series of risk assessments that led to its proposing to revoke all tolerances based on those findings.

9. As part of my job, I regularly hear heartbreaking stories from workers about illnesses related to their exposure to pesticides and the long-term consequences they have on people, including children. I have seen applicators and farmworkers suffering from horrible rashes over their hands and faces from exposure to these harmful toxins. Medical doctors often prescribe creams to ease the itching, without ever addressing the causes or taking an occupational health history of the patient. But applicators and farmworkers are not the only ones at risk. Children, the elderly, and those with lowered immune systems or allergies are much more vulnerable to the long-term consequences of pesticide exposure. Also, EPA specifically found that chlorpyrifos is harmful to children's developing brains.

10. FWAF is very concerned that chlorpyrifos will continue to harm the health of Florida farmworkers, their families and rural communities at large because of EPA's decision to leave chlorpyrifos tolerances in place after finding that the pesticide is unsafe in nearly every way it is used. We are also worried about EPA's representations that it will not respond to our objections or take any other action addressing the harms posed by chlorpyrifos until the registration review deadline of 2022. This delay leaves our members, farmworkers and their families vulnerable to exposures and at continued risk of harm and without any possibility of relief for years to come.

11. FWAF addresses many issues impacting farmworkers, from issues of inadequate housing, unfair wages and wage theft, discrimination in the workplace, harassment, job loss due

to natural disasters and much more. Addressing farmworkers' incidences of pesticide exposure and educating our members about the dangers of organophosphate pesticides like chlorpyrifos is an added burden to the already overwhelming work we undertake everyday of addressing issues of injustices against farmworkers. The amount of dollars and time spent on more research on the impacts of chlorpyrifos, when the current overwhelming science clearly points to its dangers and harms, could be better spent on other issues to help farmworkers.

12. FWAF conducted a four-year community-based research project with Emory University. As part of that study, we conducted focus groups with farmworker women of reproductive age in two different areas of the state working in two different crops. During those focus groups, we had more than one woman tell us that they had children with learning disabilities and children who did not have learning disabilities. In each case, the women had been working in agriculture when they were pregnant with their children who later were diagnosed with learning disabilities. When they were not working in agriculture, those children were born without the problem, the women in the focus groups told us.

13. FWAF has also recently partnered with University of Central Florida School of Nursing to do developmental screenings of farmworker children to look for incidences of learning disabilities and other neurodevelopmental problems. We are in the initial stages of this collaboration, but the nursing school identified these conditions as such a problem, that they felt there was great need to do these screenings and, later, referrals in our community.

14. Chlorpyrifos has been banned for residential use because of the risks to children from exposure to this pesticide. Farmworker children are children too, and no less valuable and worthy of protection than children in residential communities. Farmworker children are doubly exposed to this pesticide, from exposure in their homes and communities, and then again on the

foods that they eat. Most farmworkers cannot afford to buy organic food to feed their children. In fact, farmworker families that live close to fields might find their children eating produce out of the field without first washing it, not to mention the take home exposures that put them at greater risk. We see the affects to individuals, families, communities, and the children themselves of neurodevelopmental problems that will last their entire lives.

15. At this time, approximately 60-65% of my workload involves pesticide work, including helping to raise awareness among our supporters about the need for stronger workplace protections. Staff in our other areas also conduct health and safety trainings. They also see and interact with farmworker community members on a daily basis, including those workers who have experienced or are experiencing pesticide exposure symptoms. Almost all of our organizing staff are former farmworkers themselves with their own personal experience of working in, near or around pesticides and pesticide residues. We are hopeful that the percentage of our time addressing the tragedies of families and children affected by pesticide-related farmworker problems could be reduced if chlorpyrifos were banned. Farmworker children with learning disabilities and other neurodevelopmental problems present a public health issue that becomes a burden for schools in which these children are enrolled where there is a need for special education programs. It is also a burden to families, who are working and raising children, and who have added demands on them in dealing with offspring with neurodevelopmental problems. This is one more issue that we try to address within our organization and with our communities. My goal would be to have healthy workers and families in our communities, so that I could focus more time and attention on other important issues to our organization and our communities, such as our growing agroecology and community gardens program and the increasingly problematic

issue of heat stress among farmworkers, in addition to issues of discrimination, immigration reform, and wage theft.

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct, to the best of my knowledge, information, and belief.

Executed this 18 day of January, 2018, at Apopka, Florida


EUGENIA ("JEANNIE") ECONOMOS

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Gerardo Rios

I, GERARDO RIOS, declare and state as follows:

1. I am over the age of 18 and have personal knowledge of the statements in this declaration.
2. This declaration is being submitted in support of a lawsuit, in which the United Farm Workers (“UFW”) is a petitioner, challenging the United States Environmental Protection Agency (“EPA”) Administrator Scott Pruitt’s decision to leave chlorpyrifos tolerances in place without finding that the pesticide is safe.
3. I am currently a member of the UFW and have been a member of the union for almost 22 years since we signed our first contract in Washington State. I am the General Secretary of the worker board at my company and have volunteered and participated in many

efforts to improve the lives of farm workers because I believe in a safe and just working environment for all farm workers.

4. I live in Sunnyside, WA, a rural community, with my wife. Here we raised our 4 daughters and are now grandparents to 7 children.
5. I am currently employed as a tractor operator at a wine grape vineyard. I am a licensed pesticide applicator and my main job involves mixing insecticides, herbicides, and fungicides and applying them to the fields. I have been a farm worker for over 37 years and have worked in the fruit tree industry including nectarines, peaches, apples, cherries, and now in grapes.
6. I have been exposed to pesticides in the past while mixing and apply chemicals to the fields as part of my job. I have inhaled chemicals when my mask has come off during the mixing process.
7. My wife was also exposed to pesticides at an apple orchard where we both were employed in Washington many years ago. She began having an allergic reaction that we believe was related to her inhaling the pesticide particles in the air while working. Since then, she has suffered from allergies on a regular basis.
8. I have been a farm worker my entire adult life and I like what I do. However, I worry about the effects of pesticides on myself and my family. I do my best to protect myself and my family from the harmful effects of pesticide exposure, however there is only so much I can do to protect us and I don't have very much information about what the dangers are of different pesticides.
9. I have recently learned a little bit about the pesticide chlorpyrifos. It worries me that in the state of Washington over 200,000 pounds of this dangerous pesticide is used each

year. I don't know if I have ever been exposed to this chemical, but I worry about it being used in the area where I live and work. I also worry that residues from this pesticide could be on the food that my family and I eat which could result in health problems.

10. I do the best I can to protect myself and my family from dangerous pesticides, however I can only do so much. I hope that the EPA would be mindful of the dangers of chlorpyrifos and do something to eliminate its use and protect farm workers and our families and communities.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 12 day of January, 2018, in Sunnyside.


GERARDO RIOS

CERTIFICATE OF TRANSLATION

I, VICTORIA RUDDY, pursuant to 28 U.S.C. § 1746, declare under penalty of perjury under the laws of the United States of America that I am fluent in the English and Spanish languages and that I truly and correctly translated the foregoing declaration to the best of my ability.


VICTORIA RUDDY

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration Of Hector E. Sanchez Barba

I, HECTOR E. SANCHEZ BARBA declare and state as follows:

1. I am the Executive Director of the Labor Council for Latin American Advancement ("LCLAA"), and I have held this position for 8 years. LCLAA, formed in 1972, was founded to improve workers' rights and increase the influence of Latino workers in the political process by educating, organizing and mobilizing Latinos within and outside of the labor movement. I am submitting this declaration to describe LCLAA's interests in this litigation and in obtaining a nationwide ban on chlorpyrifos.

2. LCLAA represents the interests of more than 2 million Latino workers in the American Federation of Labor-Congress of Industrial Organizations (AFL-CIO), The Change to Win Federation, Independent Unions and all its membership. As part of our mission, we focus

on raising awareness about occupational and environmental health and safety issues that disproportionately impact Latino and immigrant workers, including farmworkers and pesticide applicators. Among our membership, we have many individuals who live and work in agricultural communities and they and their families are exposed to harmful pesticides.

3. In my work with farmworkers I've learned that they experience symptoms including rashes, blisters, nausea, and stinging in the eyes, as well as far more serious health impacts such as infertility and neurological disorders. Their children and their families are exposed to toxic pesticides through spray drift, as well as in their food and drinking water. This should not happen. I believe that all people should be afforded basic protections from harmful pesticides, including chlorpyrifos, and that is why I do this work.

4. Our members expect us to act on their behalf to obtain protections for them and their families, and as part of my job I hear and share their stories and concerns with decision makers to try and compel action. In June 2017, LCLAA joined other petitioners in this lawsuit.

5. To raise awareness about the unique experiences of farmworkers and their families and the regular exposure to pesticides that they experience, I have met with the EPA and shared stories about the reality facing farmworkers. In July 2017, our members came to Washington, DC to urge the Senate to support a bill that would ban food uses of chlorpyrifos.

6. I have shared stories from farmworker Mily Trevino-Sauceda. Mily informed me that when she was working on a citrus farm in Blythe, California, an overhead plane sprayed the fields and all the workers in it with toxic pesticides. One of her fellow farmworkers, an expectant mother, was rushed to the hospital. The baby survived, but the mother lost her life that day.

7. I have also shared the story of Florida farmworker Reina Lemus de Zelaya while advocating for better protections from pesticides. Reina's husband and daughter spoke with

LCLAA and others about their family's experience and that of farmworkers that labor in farms, nurseries and greenhouses across the state of Florida. Reina didn't realize the harms of pesticides during her time working the fields of Florida. She had yet to hear the stories of rashes, stinging eyes, blisters, nausea, headaches, respiratory problems, asphyxia, and even death that so many farmworkers routinely share. So she worked the fields through all stages of her pregnancy and even brought her baby to work, keeping her in a stroller by her side. That daughter, unlike Reina's other children, suffers from asthma, illness, and learning disabilities.

8. These stories from California and Florida echo the conditions I witnessed in labor camps in North Carolina, where farmworkers were coming home to shared rooms and due to exhaustion, laying down in the same clothes they wore while in the fields. Pesticides take longer to break down when they are indoors and if farmworkers have pesticide residues on their clothes and shoes, they are exposing their children and families to harmful chemicals.

9. We are particularly concerned about farmworker health and safety because unlike LCLAA members who traditionally rely on the Department of Labor (DOL) and the Occupational Safety and Health Administration (OSHA) to protect them from chemical exposure, farmworkers and pesticide applicators rely on the Environmental Protection Agency (EPA) to establish minimum protections from pesticide exposure via the Agricultural Worker Protection Standard (WPS) and the Certification of Pesticide Applicators (CPA) rule. These two rules are fundamental to the protection of farmworkers and their families and LCLAA advocated for the strengthening of these standards. Unfortunately, in addition to refusing to ban chlorpyrifos in our food, I am aware that in late December 2017, EPA posted to the Federal Register that it will also reconsider the safeguards provided by the WPS and CPA rule to youth and adult workers.

10. The continued use of chlorpyrifos, especially when combined with EPA efforts to weaken basic protections for farmworkers and pesticide applicators, is alarming and undermines the health and safety of farmworkers and rural communities.

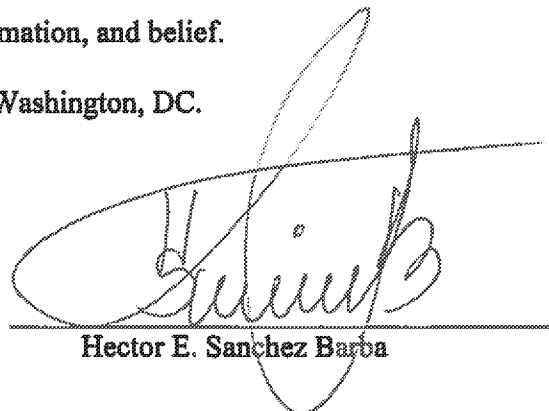
11. Our members remain concerned about their exposure to chlorpyrifos, a toxic chemical that is harmful to all people and to children in particular. I understand that EPA found that people may be exposed to chlorpyrifos through their drinking water, and that people who live in agricultural areas may be at more risk of drinking water contamination. I also understand that EPA's proposal to ban chlorpyrifos was based on unsafe drinking water exposures. I am also aware that the U.S. Department of Agriculture has detected unsafe levels of chlorpyrifos on fruits and vegetables. LCLAA members and their families may be exposed to chlorpyrifos through food and drinking water. Members that live in rural areas or that work on or near farms may also be exposed to chlorpyrifos through spray drift and occupational exposures.

12. On September 21, 2016, LCLAA, along with other petitioners in this lawsuit, submitted a Petition for Emergency and Ordinary Suspension of Chlorpyrifos Uses that Post Unacceptable Risks to Workers and Petition to Cancel All Uses of Chlorpyrifos to the United States Environmental Protection Agency ("EPA"). We also submitted comments to EPA after the agency released its 2016 revised human health risk assessment, which found that chlorpyrifos is unsafe in nearly every way that it is used.

13. I was dismayed when I learned that EPA Administrator Scott Pruitt acted against the findings and recommendations of the agency's own scientists and refused to ban chlorpyrifos in March 2017, leaving our members at disproportionate risk from this toxic pesticide. On June 5, 2017, LCLAA joined the other petitioners in filing objections with EPA and filing this lawsuit. We respectfully ask the Court to order EPA to stop delaying and act to ban chlorpyrifos.

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct, to the best of my knowledge, information, and belief.

Executed this 12th day of January 2018, in Washington, DC.



Hector E. Sanchez Barba

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

DECLARATION OF JAVIER CEJA

DECLARATION OF JAVIER CEJA

I, JAVIER CEJA, declare and state as follows:

1. I am over the age of 18 and have personal knowledge of the statements in this declaration.

2. This declaration is submitted in support of the lawsuit, in which Pineros y Campesinos Unidos del Noroeste ("PCUN") is a petitioner, challenging the delay by the United States Environmental Protection Agency ("EPA") in responding to petitioners' objections after EPA denied a petition to ban chlorpyrifos.

3. I am a founding member of PCUN, and I have been a member for over 31 years.

4. I currently live in Woodburn, Oregon. Woodburn is a small, agricultural town that is surrounded by farms and fields.

5. Based upon my personal knowledge and experience, I am very concerned about the use of dangerous pesticides, including chlorpyrifos, in the fields that I work in and live near.

6. I have been a farmworker for more than 50 years. I have worked as a farmworker in Oregon and California with various vegetable crops, fruit trees, grapes, and ornamentals. I am currently working on a grass seed farm.

7. My wife is also a farmworker, and we are both exposed to pesticides at work. I fear that we are also exposed to dangerous pesticides through spray drift and on our food.

8. I don't know the names of all the chemicals that are used on the farm that I work in because the growers almost never tell us what they are using. The chemicals are very powerful and they smell terrible. I have seen people in the fields come into contact with these pesticides and get rashes, headaches, and sometimes faint.

9. I don't know which pesticides are used around the area that I live in because they don't tell us what they are spraying or what the effects could be. I sometimes see crop dusters

spraying pesticides on fields when I am outside and I am afraid that I am being exposed to dangerous pesticides through drift.

10. I am currently in remission from cancer and I have to go in for regular check-ups. My cousin who is also a farmworker got cancer too. I don't know how I got cancer, but I have heard that pesticides can cause cancer and I think that may have been the cause.

11. I am aware that chlorpyrifos is a very toxic chemical and I believe that it should not be used on food. I am concerned about the presence of chlorpyrifos on the food that my family and I eat, especially since we are already exposed to pesticides in other ways. I would feel much safer for myself and my family if I know that chlorpyrifos was not allowed to be used on food at all.

12. I support PCUN's efforts in working to get chlorpyrifos banned. I believe that EPA's delay in responding to PCUN's objections while allowing the use of chlorpyrifos to continue causes harm to me and my family.

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct, to the best of my knowledge, information, and belief.


Executed this 28TH day of OCTOBER, 2017, at WOODBURN, OREGON

Javier Ceja.

Javier Ceja

CERTIFICATE OF TRANSLATION

I, RAMON RAMIREZ, pursuant to 28 U.S.C. § 1746, declare under penalty of perjury under the laws of the United States of America that I am fluent in the English and Spanish languages and that I truly and correctly translated the foregoing declaration to the best of my ability.

A handwritten signature in black ink, appearing to read 'Ramon Ramirez', written over a horizontal line.

Ramon Ramirez

NO. 17-71636
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

DECLARATION OF JENNIFER SASS

I, Jennifer Sass, declare as follows:

1. I am a Senior Scientist for petitioner Natural Resources Defense Council (“NRDC”).
2. NRDC is a non-profit organization whose mission is to safeguard the earth—its people, its plants and animals, and the natural systems on which all life depends.

Among NRDC's six priorities is stemming the tide of toxic chemicals. Protecting the public from the substantial adverse health effects caused by exposure to toxic chemicals, including pesticides like chlorpyrifos, is central to NRDC's mission and goals.

3. NRDC currently has over 408,000 members. NRDC members reside in each of the 50 states and the District of Columbia. NRDC members may be exposed to chlorpyrifos in the foods they eat, the water they drink, from contaminated air resulting from pesticide drift and residues taken home on clothing. Children face particularly high exposures because of the foods they eat, their higher water consumption per pound of body-weight, and the activities they engage in, like putting their hands in their mouths, that put them into contact with pesticide residues.

4. NRDC has long devoted extensive resources to protecting people from toxic pesticides. I have spent a substantial amount of time on these activities since I started working at NRDC in January 2001. I have advanced degrees in Anatomy and Cell Biology, with specific expertise in developmental biology, neurobiology, molecular biology, and environmental health. In my position with NRDC, I am responsible for reviewing the science underlying many of the federal regulations of industrial chemicals and pesticides. I have published over forty-five articles in peer-reviewed scientific journals, including many pertaining to pesticide hazards and regulations. On numerous occasions, I have provided testimony to the Environmental Protection Agency ("EPA"), both written and oral, on the registration of dozens of pesticides during its registration process.

5. I represented NRDC for over a decade as an active member of the EPA/U.S. Department of Agriculture ("USDA") Pesticide Program Dialogue Committee ("PPDC"), a stakeholder committee that provides feedback to the EPA Office of Pesticide Programs on

various issues related to pesticide regulatory, policy, and program implementation issues.

Through my years of work on the PPDC, from 2001 to 2013, I also served on issue-specific PPDC workgroups to provide more in-depth perspectives and advice on pesticide issues. I was also a member of the EPA/USDA Committee to Advise on Reassessment and Transition (“CARAT”) from 2001 until the committee disbanded in 2003. The purpose of CARAT was to provide advice on strategic approaches for pest management planning, transition, and tolerance reassessment for pesticides as required by the Food Quality Protection Act (“FQPA”).

6. NRDC has been extensively engaged in advocacy and scientific analysis to obtain revocation of chlorpyrifos tolerances. In addition to the 2007 Petition, we submitted comments on EPA risk assessments and the proposed revocation rule and provided comments to Scientific Advisory Panels. *See, e.g.*, Administrative Record 995, 1025, 1512, 1526.

7. In this declaration, I provide background about the pesticide chlorpyrifos and the significant human health risks that it poses, particularly to children. I also describe the petition that NRDC and Pesticide Action Network North America (“PANNA”) submitted to EPA in September of 2007, which asked EPA to ban food uses for chlorpyrifos and revoke all tolerances (maximum residue levels allowed on food) for chlorpyrifos. I describe the EPA Administrator’s March 29, 2017 Order denying that petition, and the harm that is being caused during EPA’s ongoing delay in taking effective and enforceable action to protect people, especially children, from chlorpyrifos.

Background on Chlorpyrifos

8. Chlorpyrifos is one of the most widely used insecticides in the United States. It is used on various food and feed crops. According to 2015 U.S. Geologic Service data – the most

recent data publicly available - approximately five to seven million pounds of chlorpyrifos are applied annually in U.S. agriculture, with widespread use on corn, orchards and grapes.

9. Chlorpyrifos is an organophosphate pesticide. Organophosphates (also referred to as organophosphorus pesticides or OPs) are a class of chemicals originally developed many decades ago; some were used during World War II as nerve agents. They kill insects by overstimulating the nervous system, ultimately leading to its collapse.

10. For the same reason that they are effective pesticides, OPs can exert strong adverse effects on the human nervous system.

11. One key nervous system effect of OPs is known as “cholinesterase inhibition,” in which the pesticide interferes with the function of one of the body’s proteins, an enzyme called cholinesterase. Cholinesterase is necessary to degrade one of the nervous system’s key messengers, acetylcholine, in a timely manner. When OPs are in the system, the cholinesterase enzyme cannot do its job to degrade acetylcholine. Acetylcholine is a neurotransmitter protein that carries messages from the brain and spinal cord out to muscle cells and other cell receptors where it activates skeletal muscles, inhibits heart muscle, and aids in memory formation, learning, attentiveness, and other critical nervous system functions. OP exposure leads to a build-up of acetylcholine and prolonged over-activation of acetylcholine receptor cells. The result of OP exposure can vary in people depending on the dose and differences in ages, health status, and other factors. Effects can include headaches, nausea, dizziness, restlessness, muscle twitching, weakness, tremor, poor coordination, confusion, difficulty breathing, vomiting, and diarrhea. At very high exposures, more serious effects such as convulsions, respiratory paralysis, and death have been reported. Poisoning can occur through any route of exposure, including inhalation, ingestion, eye contact, and absorption through the skin.

Children are especially sensitive to harm from chlorpyrifos exposure.

12. Children are especially sensitive to harm from chlorpyrifos exposure.

13. Per pound of body weight, children eat, drink, and breathe more than adults. For example, EPA's Exposure Factors Handbook reports that the average bottle-fed newborn drinks 52 milliliters of water per kilogram body weight per day (mL/kg-day) and the highest five percent of bottle-fed babies drink 232 mL/kg-day, whereas a one-year old drinks half that amount (23 mL/kg-day average and 71 mL/kg-day at the top five percent). The average adult drinks half that amount again (13 mL/kg-day average and 40 mL/kg-day at the top five percent).¹

14. Infants, toddlers, and young children are more likely to play on the ground and engage in more frequent hand- to-mouth contact than adults, and therefore have higher rates of dermal and oral exposure from pesticide-contaminated objects, dust, or soil. EPA's Exposure Factors Handbook reports that during indoor activities babies, six to twelve months old put their hands to their mouths an average of 19 times per hour, and five percent of babies do it 52 times per hour, whereas adults do it rarely.² These age-related activities mean that infants and young children are much more likely to have greater chlorpyrifos exposures than adults, when adjusted for body weight.

15. In addition, infants and children are especially susceptible to chemical toxicity compared with adults. Children's bodies have immature detoxification mechanisms compared with adults, and chemical assault during development of critical target organs and systems can

¹ U.S. EPA. Exposure Factors Handbook 2011 Edition (Final). U.S. Environmental Protection Agency, Washington, D.C., EPA/600/R-09/052F, 2011. See Chapter 3, Table 3-1 on drinking water ingestion rates by age. <https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252>

² U.S. EPA. Exposure Factors Handbook 2011 Edition (Final). U.S. Environmental Protection Agency, Washington, D.C., EPA/600/R-09/052F, 2011. See Chapter 4, Table 4-10 on indoor hand-to-mouth frequency by age. <http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252>

cause disruptions that are then hard-wired into the developing system.³ For example, extensive research on lead and mercury demonstrates that during neural development the nervous system is acutely vulnerable to neurotoxic assault, and exposures may result in long-term or permanent destruction or dysfunction to systems including learning, memory, and intelligence. This is also true for the developing immune system, endocrine system, and reproductive system. For example, doses of lead or mercury with no obvious effect on adults can cause permanent measurable brain damage in exposed children. For this reason, studies on adults, including adult laboratory animals, will under-predict risks to fetuses, infants, and children. The scientific consensus is that early life developmental stages are particularly vulnerable to toxic exposures.⁴

The Food Quality Protection Act

16. Because infants and children are especially sensitive, the National Academy of Sciences' landmark 1993 report, "Pesticides in the Diets of Infants and Children," made the scientific case to overhaul of EPA's pesticide program to assure the safety of children, citing OPs as one of the classes of pesticides of concern.⁵ This report was widely cited as the catalyst for the enactment of the unanimously passed Food Quality Protection Act (FQPA), which significantly overhauled the pesticide regulatory framework.

³ Huen K, Harley K, Brooks J, et al. Developmental Changes in PON1 Enzyme Activity in Young Children and Effects of PON1 Polymorphisms. *Environmental Health Perspectives*. 2009;117(10):1632-1638. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2790521/>

⁴ National Research Council. 1993. Pesticides in the Diets of Infants and Children. Washington, DC: The National Academies Press.

⁵ Pesticides in the Diets of Infants and Children (Washington, D.C.: National Academy Press, 1993).

17. The FQPA recognizes that the previous law insufficiently protected infants and children. It therefore mandates that EPA use an additional ten-fold safety factor in its assessments to address toxicity to infants and children and gaps in information on toxicity or exposure.

18. The FQPA requires EPA to protect children from aggregate exposures to each pesticide. Whereas EPA previously assessed exposure to a pesticide in various foods individually, it must now aggregate all the routes by which children are exposed to each pesticide. EPA must therefore evaluate children's exposures to chlorpyrifos through consuming foods with residues of chlorpyrifos, drinking water contaminated with chlorpyrifos, and drift from fields.

19. The FQPA also requires EPA to evaluate the cumulative effects of people's exposure to all pesticides that share a common mechanism of toxicity. Because all the OPs attack the human nervous system in essentially the same way, EPA has determined that they share a "common mechanism of toxicity," as described in the FQPA. Therefore, EPA developed has spent a decade developing a cumulative risk assessment for the OPs.

20. Because of the high risk that OPs pose to people, and especially to children, EPA took protective measures to cancel almost all the residential uses of the OPs in 2000. This resulted in a significant and measurable reduction in poisonings to children from roach baits, residential foggers or "bug bombs," and other homeowner uses.

21. However, the cancelations left children living in agricultural areas at direct risk from all the agriculture uses that remained, and led to continuing contamination of our food supply and waterways including sources of drinking water.

22. Children of farmworkers and those living in agricultural communities are heavily exposed to pesticides, including chlorpyrifos. Children in agriculture communities may come in

contact with pesticides through residues on their parents' skin and clothing, contaminated soil in their play areas, pesticide-laden dust tracked into their homes, drift from chlorpyrifos applications, contaminated air and drinking water, residues on produce, and even breast milk. Furthermore, these children may accompany their parents to work in the fields or help by working themselves, thus experiencing high or occupational levels of exposure.⁶ Children of farmworkers are also exposed to pesticides prenatally, when pregnant women are exposed to pesticides during their work.

Despite Evidence of Harm, EPA's Previous Evaluation Allowed Chlorpyrifos To Remain on the Market

23. In 2001, EPA completed the chlorpyrifos aggregate assessment, called an Interim Reregistration Eligibility Decision ("IRED"), which revised but retained many of the pre-existing food tolerances (allowable residue limits on food).⁷ In its 2002 comments on the IRED (Docket ID No. OPP-34203G), NRDC challenged the scientific limitations of the IRED, identified evidence of harm, and highlighted that there is inadequate evidence to establish an exposure level at which infants and children will not suffer any developmental harm due to chlorpyrifos exposure, i.e. a "no observable adverse effect level" or NOAEL. EPA never responded directly to NRDC's comments or other comments submitted by other public interest advocates, including Pesticide Action Network and the New York Attorney General.

⁶ Engel SM, Bradman A, Wolff MS, Rauh VA, Harley KG, Yang JH, Hoepner LA, Barr DB, Yoltan K, Vedar MG, Xu Y, Hornung RW, Wetmur JG, Chen J, Holland NT, Perera FP, Whyatt RM, Lanphear BP, Eskenazi B. 2016. Prenatal organophosphorus pesticide exposure and child neurodevelopment at 24 months: an analysis of four birth cohorts. *Environ Health Perspect* 124:822-830.

⁷ 66 Fed. Reg. 57,073 (Nov. 14, 2001) Organophosphate Pesticide; Availability of Chlorpyrifos Interim Risk Management Decision Document. IRED at 64-68.

24. In 2006, EPA completed the cumulative risk assessment for all OPs, including chlorpyrifos, and reaffirmed the chlorpyrifos IRED without change, despite new, significant published studies that had emerged during this time showing harm to the developing brain of children. Without addressing the comments by NRDC and others, the Agency concluded that chlorpyrifos uses would be eligible for reregistration and tolerances with a few limitations on some uses.⁸

2007 Petition to EPA to Cancel Chlorpyrifos and Revoke All Tolerances

25. In 2007, I coauthored the “Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos” (the “2007 Petition”), which was submitted to EPA. That document was submitted to EPA on behalf of PANNA and NRDC on September 12, 2007. The 2007 Petition focused on scientific evidence of the long-lasting effects to children from early life chlorpyrifos exposure, as well as exposures through air contamination from pesticide drift and volatilization.

26. The 2007 Petition presented a robust body of scientific information laying out the human health risks associated with chlorpyrifos, and those risks particularly relevant to children and infants, which is sufficient to justify EPA revoking all tolerances and cancelling all registrations for chlorpyrifos. That evidence is described in more depth in the 2007 Petition.

27. Scientific evidence that has emerged since 2001 and since we submitted the 2007 Petition further supports the revocation of all tolerances and cancellation of all registrations for chlorpyrifos.

⁸ Memo from Debra Edwards to Jim Jones, re: Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides, July 31, 2006.

Children Have Long-Lasting Effects from Early Life Exposure to Chlorpyrifos

28. EPA found that different types of studies including animal toxicology to human epidemiology examining the impact of early-life chlorpyrifos exposure consistently show that prenatal exposure to chlorpyrifos, including some studies that show that levels too low to trigger effects in adults cause adverse neurodevelopmental and neurobehavioral effects.

29. Animal studies show that the animals exposed prenatally to chlorpyrifos suffer neurodevelopmental adverse effects, including some recent studies correlating such effects with exposures below levels that caused ten percent or more cholinesterase inhibition in the pregnant adult rat. The effects caused by chlorpyrifos during neurodevelopment in test rodents are associated with impaired learning and working memory as the rodents mature, demonstrating persistent functional effects.⁹

30. Human population studies strengthen the evidence that exposure to chlorpyrifos during pregnancy can cause lasting neurodevelopmental harm, even at doses too low to cause cholinesterase inhibition to the pregnant mother. Multiple epidemiologic studies in diverse populations spanning urban and agricultural settings have shown significant links between lasting deficits in brain development and function and prenatal exposure to OPs generally and to chlorpyrifos specifically.¹⁰

⁹ Levin ED, Addy N, Baruah A, Elias A, Christopher NC, Seidler FJ, Slotkin TA. Prenatal chlorpyrifos exposure in rats causes persistent behavioral alterations. *Neurotoxicol Teratol*. 2002 Nov-Dec;24(6):733-41.

¹⁰ Muñoz-Quezada MT, Lucero BA, Barr DB, Steenland K, Levy K, Ryan PB, Iglesias V, Alvarado S, Concha C, Rojas E, Vega C. Neurodevelopmental effects in children associated with exposure to organophosphate pesticides: a systematic review. *Neurotoxicology*. 2013 Dec;39:158-68.

González-Alzaga B, Lacasaña M, Aguilar-Garduño C, Rodríguez-Barranco M, Ballester F, Rebagliato M, Hernández AF. A systematic review of neurodevelopmental effects of prenatal

31. A team of Columbia University researchers have an important, ongoing longitudinal study that began in 1997. It includes mothers and their children who were born between February 1998 and May 2002.¹¹ The study provides a unique opportunity for the researchers to measure the public health impact of the EPA ban on the sale of chlorpyrifos products for residential uses, announced in June 2000. Researchers measured a dramatic drop in exposure levels in the children born after the ban took effect. Residential air samples decreased three-fold and newborn infant plasma cord blood levels at birth decreased over five-fold among women and their babies in the study.¹²

32. The Columbia University researchers have been following and reporting on the progress of the children born into the study. At age three, the researchers reported that based on performance in standardized tests the children with the highest levels of chlorpyrifos at birth were five times more likely to have delayed development of physical movement like dexterity and fine motor control, and 2.4 times more likely to have delayed mental development, compared with the children with the lowest levels at birth.¹³ Adverse neurobehavioral effects

and postnatal organophosphate pesticide exposure. *Toxicol Lett.* 2014 Oct 15;230(2):104-21. doi:10.1016/j.toxlet.2013.11.019. Epub 2013 Nov 26. Review.

¹¹ Whyatt RM, Barr DB, Camann DE, Kinncy PL, Barr JR, Andrews HF, Hoepner LA, Garfinkel R, Hazi Y, Reyes A, Ramirez J, Cosme Y, Perera FP. Contemporary-use pesticides in personal air samples during pregnancy and blood samples at delivery among urban minority mothers and newborns. *Environ Health Perspect.* 2003 May;111(5):749-56.

¹² Rauh VA, Garfinkel R, Perera FP, Andrews HF, Hoepner L, Barr DB, Whitehead R, Tang D, Whyatt RW. Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children. *Pediatrics.* 2006 Dec;118(6):e1845-59.

Also, see comments to EPA from Dr. Dale Hattis. Table 35. April 16, 2016. Doc ID: EPA-HQ-OPP-2016-0062-0121.

¹³ Rauh VA, Garfinkel R, Perera FP, Andrews HF, Hoepner L, Barr DB, Whitehead R, Tang D, Whyatt RW. Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children. *Pediatrics.* 2006 Dec;118(6):e1845-59.

include attention problems, attention-deficit/hyperactivity disorder (ADHD) problems, and long-lasting developmental disorder problems.

33. The Columbia University researchers reported that at age eleven, arm tremors (measured using standardized tests involving drawing specific spiral shapes) in the children with highest chlorpyrifos exposures (as measured in the cord blood at birth).¹⁴ This suggests that prenatal chlorpyrifos exposure may cause an even broader scope of effects, including latent or long term development of fine motor control that may not become obvious for over a decade or more.

34. Adverse consequences appear to extend into late childhood and adolescence. Forty of the children in the Columbia University study were examined at six to eleven years old using magnetic resonance imaging to look at brain structures. In the twenty children with the highest prenatal chlorpyrifos exposure, the researchers observed unusual thinning and deformed areas in the outer areas of the brain, called the cortex, in regions specific for social cognition and emotional control.¹⁵ The twenty low-exposure children did not have these structural brain alterations.

35. A recent study of Chinese infants by a collaboration of scientists from the University of Michigan and a children's hospital and medical university in China reported similar findings to those of the Columbia University team. The Chinese infants exposed prenatally to chlorpyrifos had poorer reflexes, grasping, and locomotion skills when compared to

¹⁴ Rauh VA, Garcia WE, Whyatt RM, Horton MK, Barr DB, Louis ED. Prenatal exposure to the organophosphate pesticide chlorpyrifos and childhood tremor. *Neurotoxicology*. 2015 Dec;51:80-6. 0

¹⁵ Rauh, V. A., Perera, F. P., Horton, M. K., Whyatt, R. M., Bansal, R., Hao, X., ... Peterson, B. S. (2012). Brain anomalies in children exposed prenatally to a common organophosphate pesticide. *Proceedings of the National Academy of Sciences of the United States of America*, 109(20), 7871–7876.

unexposed infants.¹⁶ The authors suggest these delays in early motor skills may possibly lead to later life developmental delays in both physical and mental abilities.

36. The Childhood Autism Risks from Genetics and Environment study showed that applying OPs in agricultural fields within 1.5 kilometers of the home of a woman while she is pregnant is associated with an increased incidence of autism spectrum disorders in the prenatally exposed child, and the risk was most elevated for chlorpyrifos.¹⁷ Chlorpyrifos was the most abundant and widely used of all the pesticides reported in the study.

Scientific Advisory Panels agree that cholinesterase inhibition is not a protective endpoint.

37. Based on the large and convincing body of scientific evidence from high quality animal toxicology and human epidemiology studies, the EPA's Scientific Advisory Panels (SAP), building on findings made by the SAP in 2008, in 2012 and in 2016 agreed that relying on a threshold of no higher than ten percent cholinesterase inhibition as a NOAEL level does not account for neurodevelopmental effects and is not sufficiently protective of the American population. The SAPs' largest concern was for prenatally exposed children, where long-lasting and possibly permanent deficits in learning, working memory, and anti-social behavior was reported.

38. In the 2016 review, "[t]he Panel agrees that both epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos

¹⁶ Silver MK, Shao J, Zhu B, Chen M, Xia Y, Kaciroti N, Lozoff B, Meeker JD. Prenatal naled and chlorpyrifos exposure is associated with deficits in infant motor function in a cohort of Chinese infants. *Environ Int.* 2017 Sep;106:248-256.

¹⁷ Shelton JF, Geraghty EM, Tancredi DJ, Delwiche LD, Schmidt RJ, Ritz B, Hansen RL, Hertz-Picciotto I. Neurodevelopmental disorders and prenatal residential proximity to agricultural pesticides: the CHARGE study. *Environ Health Perspect.* 2014 Oct;122(10):1103-9. Erratum in: *Environ Health Perspect.* 2014 Oct;122(10):A266.

exposures below levels that result in [ten percent cholinesterase inhibition] (i.e., toxicity at lower doses).”¹⁸ The SAP recommended that EPA continue to work to account for that neurodevelopmental impacts in children from prenatal exposures occur even at levels below those that cause detectable cholinesterase inhibition in the pregnant mother.

EPA Finds Food Residue Exposure Alone Is Unsafe

39. In the 2016 assessment, EPA found that food exposures for young children (one to two years old) were up to 140 times greater than EPA’s target risk threshold. Food exposures for pregnant women were found to be 62 times greater than the target risk threshold to protect against harm to the developing brain. EPA’s exposure analysis identified ten food crops where more than 25 percent are grown with chlorpyrifos.¹⁹ Regular residue testing performed by the USDA (and summarized in EPA’s food exposure analysis) routinely finds residues on these crops and others.²⁰

40. Children face significant risk from chlorpyrifos residues in the diet because USDA testing finds chlorpyrifos residues on the top fruit consumed by children – apples make up approximately 36 percent of non-juice related daily fruit intake – even after washing.^{21 22}

¹⁸ Transmittal of Meeting Minutes of the April 19-21, 2016 FIFRA SAP Meeting Held to Consider and Review Scientific Issues Associated with “Chlorpyrifos: Analysis of Biomonitoring Data”. July, 2016. Report and other meeting materials available at: <https://www.epa.gov/sap/meeting-materials-april-19-21-2016-scientific-advisory-panel> p.20

¹⁹ Experts Support EPA Proposed Ban on Chlorpyrifos. January 17, 2017 Jennifer Sass <https://www.nrdc.org/experts/jennifer-sass/experts-support-epa-proposed-ban-chlorpyrifos>

²⁰ EPA: Toxic Pesticide on Fruits, Veggies Puts Kids at Risk. January 06, 2017 Miriam Rotkin-Ellman and Veena Singla <https://www.nrdc.org/experts/miriam-rotkin-ellman/epa-toxic-pesticide-fruitsveggies-puts-kids-risk>

²¹ Herrick KA, Rossen LM, Nielsen SJ, Branum AM, Ogden CL. Fruit Consumption by Youth in the United States. *Pediatrics*. 2015;136(4):664-671. doi:10.1542/peds.2015-1709.

²² USDA Pesticide Data Program.

Similarly, chlorpyrifos residues are found on other fruits popular with children:

peaches/nectarines, citrus (even peeled), grapes, berries, and melon (even under the rind).

41. In the most recent USDA pesticide residue testing data available (2015), chlorpyrifos residues were found on twelve different types of fruits and vegetables, which was 71 percent of the seventeen crops tested.²³

EPA Finds Drinking Water Exposure Alone is Unsafe

42. In its 2014 and 2016 assessment, EPA calculated that many of the legally permitted uses of chlorpyrifos result in drinking water contamination levels that exceed EPA's levels of concern.²⁴

43. In its 2014 assessment, EPA found that children would be exposed to unsafe levels of chlorpyrifos from drinking water contamination alone, even before considering additional daily routes of exposure including food.

44. For its 2016 Refined Drinking Water Assessment, EPA performed additional analyses to assess potential chlorpyrifos drinking water exposures based on national and regional modeling information as well as real-world water monitoring data. All analyses showed that drinking water concentrations across the country exceed the drinking water level of concern, presuming that there is no food exposure. The assessment confirmed the Agency's previous findings that "the majority of estimated drinking water exposures from currently registered uses, including water exposures from non-food uses, continue to exceed safe levels even taking into account more refined drinking water exposures."

²³ USDA 2015. Pesticide Data Program, Annual Summary, Calendar Year 2015.

²⁴ 80 Fed. Reg. 69,079, 69,083 (Nov. 6, 2015)

45. Unsurprisingly, EPA also found that higher concentrations of chlorpyrifos and the more potent chlorpyrifos-oxon are likely to be found in areas with higher agriculture uses of chlorpyrifos. Thus, agricultural communities, including farmworkers and their families, are more likely to have their drinking water contaminated by chlorpyrifos.

EPA's Failure to Revoke all Chlorpyrifos Tolerances and Cancel Registrations for Food Uses Is Causing Harm to NRDC and its Members

46. On March 29, 2017, EPA Administrator Scott Pruitt denied the 2007 petition (the "Pruitt Order"), because he chose to engage in "further evaluation of the science" on the "adverse neurodevelopmental effects to occur from current human exposures to chlorpyrifos" before finalizing the proposed revocation of chlorpyrifos tolerances. He indicated that this further evaluation would take place during the registration review process, which has a statutory deadline of October 1, 2022.

47. Because of EPA's failure to act on the pending petition, NRDC members and their children are being exposed to unsafe levels of chlorpyrifos on food, in drinking water, and in pesticide drift and volatilization, and will continue to be as long as the chlorpyrifos registrations and food tolerances remain in effect.

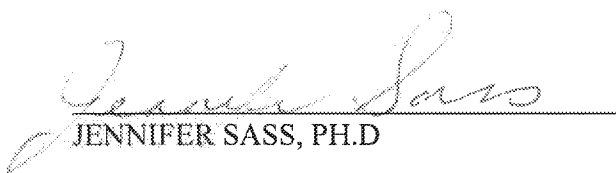
48. In addition, EPA's failure to revoke chlorpyrifos tolerances and end food uses of chlorpyrifos has led NRDC to devote extensive resources to compiling and disseminating information about the risks of chlorpyrifos. Drawing on the frequent detection of residues on fruits consumed regularly by children in government surveys, NRDC compiled and prepared information for the public in the form of online articles, media briefing information, and fact sheets to help parents and others understand what EPA's assessment means for their family. For example, NRDC highlighted the fact that many fruits that kids regularly eat, including apples,

peaches, and strawberries, have chlorpyrifos residues in the fruit even after they are washed and peeled.²⁵ NRDC also pointed out that chlorpyrifos residues are also routinely found on imported fruits like peaches, grapes, and melons.

49. EPA's failure to enact the proposed tolerance revocations has resulted in state-based efforts to eliminate or reduce risk to their residents. NRDC has spent significant resources advocating along with partners for a ban on chlorpyrifos in California. These efforts have resulted in designation of chlorpyrifos as a restricted use pesticide, a proposal to have it designated as a toxic air contaminant, and a proceeding which added chlorpyrifos to the Proposition 65 list of reproductive chemicals that may require warnings to the public. NRDC has provided technical analyses to inform California scientific bodies and regulators of the science and risks posed by chlorpyrifos and the dangerous exposures identified in California's agricultural communities.

50. This investment of resources would not be necessary if EPA had complied with its obligations and revoked chlorpyrifos tolerances because it cannot find the pesticide safe.

Pursuant to 28 U.S.C. §1746, I declare under penalty of perjury that the foregoing is true and correct, to the best of my knowledge. Executed this 23 day of January, 2018, in Washington, D.C.


JENNIFER SASS, PH.D

²⁵ EPA: Toxic Pesticide on Fruits, Veggies Puts Kids at Risk. NRDC Expert blog, by Miriam Rotkin-Ellman and Veena Singla. January 6, 2017. <https://www.nrdc.org/experts/miriam-rotkin-ellman/epa-toxic-pesticide-fruitsveggies-puts-kids-risk>

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Jose Cruz

I, JOSE CRUZ, declare and state as follows:

1. I am over the age of 18 and have personal knowledge of the statements in this declaration.

2. This declaration is being submitted in support of a lawsuit, in which the United Farm Workers ("UFW") is a petitioner, challenging the United States Environmental Protection Agency ("EPA") Administrator Scott Pruitt's decision to leave chlorpyrifos tolerances in place without finding that the pesticide is safe.

3. I am a member of the United Farm Workers union. I have been a member for about 19 years. I am a member of the worker board and have a great deal of protections under

my union contract. However, other farm workers do not benefit from the same protections and I believe that all farm workers should have health and safety standards at work.

4. I live in Sunnyside, Washington and have two young daughters, ages 8 and 10.

5. I have been a farm worker for 20 years and currently work as a pesticide applicator at a vineyard. My job involves mixing pesticides and spraying them onto the fields. We apply lots of different types of pesticides, but I am not sure what the name of each pesticide is.

6. I have been exposed to pesticides while at work on two occasions. Once I was involved in an accident when a coworker left a sprayer on and I was sprayed by a pesticide. I don't remember what chemical I was sprayed with. My face was not fully protected and I got the pesticide on my skin. On another occasion, several coworkers and I were exposed to aerial drift when a dusting plane was spraying pesticides on a neighboring field. We began to inhale the pesticides that were drifting onto the field where we were working and workers started getting concerned and told the supervisor. A few workers began to feel sick after inhaling the pesticides.


7. I have a lot of concern about my exposure to pesticides, as I come in contact with pesticides on a regular basis at work. I have been mixing and applying pesticides for many years and I have spoken with other farm workers that I know personally who have gotten sick after long time exposure to pesticides in the fields. I worry that I might get sick because of my contact with pesticides.

8. I don't know whether I have ever been exposed to chlorpyrifos, but it does worry me because it is a very dangerous and toxic pesticide. I would feel much better knowing that this pesticide wasn't being applied to the food that I feed my family or being sprayed near my home or my work.

9. I feel that the EPA is putting farm workers and their families in danger by not prohibiting the use of Chlorpyrifos. They are ignoring our health and safety by allowing us to be exposed to this dangerous pesticide. If this pesticide was banned from use in our communities we would all be much safer.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 12 day of January, 2018, in Sunnyside.


JOSE CRUZ

CERTIFICATE OF TRANSLATION

I, VICTORIA RUDDY, pursuant to 28 U.S.C. § 1746, declare under penalty of perjury under the laws of the United States of America that I am fluent in the English and Spanish languages and that I truly and correctly translated the foregoing declaration to the best of my ability.


VICTORIA RUDDY

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

DECLARATION OF JUDY FISHMAN

DECLARATION OF JUDY FISHMAN

I, JUDY FISHMAN, declare and state as follows:

1. I have been a member of the Natural Resources Defense Council since 1999, and I support NRDC's efforts to protect the public from exposure to harmful pesticides.

2. I am 72 years old and live in Los Angeles, California.

3. My husband and I have three grown children and five grandchildren between the ages of four and seventeen. They live in Los Angeles and San Francisco, CA.

4. I am aware that chlorpyrifos and other organophosphate pesticides are widely used and can have negative impacts on our physical health and our mental health. I am concerned about the health impacts caused by chlorpyrifos, and the overall impacts of exposure to chlorpyrifos and other pesticides.

5. I am very concerned about my grandkids who eat a lot of fruit and are still growing. As much as their parents try, my grandchildren do not eat just organic food. I am concerned that my grandchildren are putting substances in their bodies that are going to cause them health and cognitive issues for a lifetime. I am concerned about how these pesticides may stay in their bodies during puberty that will affect their children and future generations.

6. I am concerned about all kids being exposed to pesticides on food because eating organic food to avoid pesticides isn't an option for most children. If kids eat in schools, other homes, restaurants, any place outside the home, they are not eating organic the bulk of the time.

7. I am concerned about the widespread use of chlorpyrifos and other pesticides. There is no way for me to detect if it is on what I'm eating and what my grandchildren are eating. Even if we try to eat healthily, by eating fruits and vegetables, we can guess that we are eating food with chlorpyrifos and other pesticides.

8. I have a Master's degree in Educational Psychology with a specialty in Parent Education and Child Development. I worked as an Educational Therapist and ran parent education programs for ten years. I helped found the Children's Nature Institute, an environmental education program that taught our youngest children and served thousands of inner city kids during the 30 years it was in Los Angeles.

9. In my work, I saw what inner-city kids ate when we bused them to our programs. While most of it was unhealthy, when it was healthy, it was foods that were likely affected by chlorpyrifos like apples, grapes, strawberries. These kids need all the help they can get to eat healthy and to thrive in this world. Many of the kids we served were already challenged by poverty, developmental delays, lack of school readiness

and toxic stress. Some were homelessness, in foster care or being raised by teen parents. Most had poorly educated parents struggling with poverty and some were affected by the opioid crisis. Adding another problem, such as developmental issues, on top of what they are already dealing with has a much more profound effect on their lives.

10. I am concerned that like other pesticides, chlorpyrifos is getting into our food chain, including food my family and I eat. Once in the food chain, it is there permanently. It could take years to get rid of it, if ever.

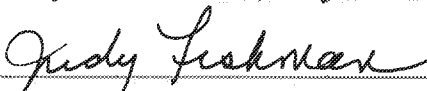
11. I am concerned because chlorpyrifos is a drift pesticide (making it even more toxic and pervasive), and that it's in schools and homes in farming areas such as the California Central Valley. It is negatively affecting children's development and therefore the future of our country.

12. Chlorpyrifos has been proven to lower the IQ of our children who need math, science, and cognitive skills to function in our rapidly changing world. I am concerned that the impact of chlorpyrifos on children's neurodevelopment is undermining our future economy and the health of our country. I am concerned that chlorpyrifos is making our population more vulnerable.

13. I am aware that the Natural Resources Defense Council petitioned the U.S. Environmental Protection Agency to ban chlorpyrifos in 2007. I am also aware that the NRDC has been part of several lawsuits about that petition. I am aware that the NRDC has filed objections to EPA on chlorpyrifos, but that EPA has not responded to those objections.

14. I believe that EPA cannot wait any longer to take action on chlorpyrifos.

Executed this 12 day of January, 2018, at 1:16 pm Los Angeles, Ca 90049



JUDY FISHMAN

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Margaret Reeves

I, MARGARET REEVES, declare and state as follows:

1. I am a senior scientist at Pesticide Action Network of North America (“PANNA”).
2. I have a Ph.D. in Agricultural Ecology from the University of Michigan (1991), and I spent two years of post-doctoral research in Agronomy at Ohio State University (1991-1993). Before joining PANNA in 1996, I spent about nine years in Central America, teaching and conducting research in tropical agricultural ecology. I worked with university colleagues and Non-Governmental Organizations to improve productivity of low-input, ecologically sound agricultural methods. I have published articles, in both Spanish and English, in professional and popular/educational journals.

3. I also have a long-standing interest in working on behalf of people at risk of exposure to dangerous pesticides. I've been an advocate for farmworkers since the early 1980s when I volunteered in the Ann Arbor, MI support group for the Ohio-based Farm Labor Organizing Committee. Since coming to PANNA in 1996, I have continued to support the work of farmworker unions and work with members of farmworker communities in California to document exposure to harmful pesticides and to improve workplace and public health policies to better protect against such exposures.

4. As a senior scientist, I conduct research to support the organization's advocacy campaigns seeking stricter regulation of dangerous pesticides, better enforcement of existing regulations, and stronger incentives for less toxic alternatives. For example, I work with rural communities to collect data about pesticide exposure. I also monitor peer-reviewed scientific literature to keep abreast of the health hazards associated with exposure to specific pesticides. I educate the public about my research findings by writing reports and contributing to PANNA's blog. In addition, I share my findings during regular conference calls and other communications with PANNA's allies, including grassroots community groups and farmworker unions. Many of these organizations lack the resources to hire staff scientists and, therefore, rely on my research and PANNA's expertise to educate their members about the risks of pesticide exposure, as well as the substance and adequacy of existing state and federal regulations governing pesticide use.

PANNA'S MISSION AND ACTIVITIES TO REDUCE AND ELIMINATE EXPOSURE TO TOXIC PESTICIDES

5. PANNA is a non-profit advocacy and education organization that was founded in 1982 and is dedicated to preventing harm to the public from pesticides. PANNA focuses on two related goals: (1) protecting people from exposure to dangerous pesticides; and (2) promoting a shift to less toxic alternatives. PANNA is the North American branch of the Pesticide Action

Network, an international coalition of hundreds of public interest organizations in more than 90 countries. The network challenges the global proliferation of pesticides, defends basic rights to health and environmental quality, and works to ensure the transition to a just and viable society.

6. The total number of PANNA members and supporters is about 115,000. In the past six months PANNA, members took over 19,000 PAN-facilitated actions urging their state and national representatives to ban chlorpyrifos because of their concerns about the serious human health and environmental effects of organophosphate pesticides in general, and chlorpyrifos in particular. These members have expressed particular concerns about exposure of their children to pesticides. PANNA and its members, are very concerned that EPA is failing to protect people, including PANNA members, in rural communities from chlorpyrifos and other organophosphate pesticides.

HARM FROM CHLORPYRIFOS

7. Chlorpyrifos and other organophosphates are nerve toxin insecticides. They cause numerous acute poisonings every year. Acute pesticide poisoning refers to adverse health effects associated with exposure to pesticides that occur immediately or shortly following the exposure. Acute effects from chlorpyrifos exposures include irritation of eyes, nose and throat; skin irritation; respiratory difficulty; headache; exhaustion; blurred vision; stomach cramps and vomiting; excessive salivation; tremors, staggering gait and dizziness; numbness; chest tightness; and excessive sweating. These effects may be of short duration, last days or weeks, or, in some cases, lead to long-term effects such as chronic neurological problems. Acute effects often lead to temporary job loss and loss of income.

8. Every year, the California Department of Pesticide Regulation's ("DPR") reports the number of acute poisonings. These numbers are likely to be serious underestimates of actual poisonings since most acute poisonings are never reported. See Reeves, M., A. Katten and M.

Guzmán. 2002. Fields of Poison 2002: California farmworkers and pesticides. Pesticide Action Network, San Francisco, CA. The report is available online at:
<http://www.panna.org/sites/default/files/FieldsofPoison2002Eng.pdf>.

9. Of the reported poisonings in California, fifty-one percent from 1998 to 2006 occurred when pesticides drifted from the site of application onto workers. Another 25% resulted from dermal contact with pesticide residues in fields. Chlorpyrifos was among the top five chemicals in the reported poisonings.

10. These data only address the most serious short-term poisoning incidents. There are ample data elsewhere that show that pesticides, including chlorpyrifos, have long-term, chronic adverse health effects on farmworkers. Those effects include nervous system damage, development problems, hormone disruption, immune system damage, cancer, reproductive effects, and birth defects.

11. Extensive discussion of these issues is provided in the PANNA Fields of Poison 2002 report (previously cited) that I co-authored with United Farm Workers (UFW), and California Legal Rural Assistance Foundation (CRLAF), and published in collaboration with Californians for Pesticide Reform. It revealed that pesticide safety laws fail to protect many of the California's 700,000 farmworkers and their families from poisonings even when the laws are followed. For that reason, PANNA believes that human pesticide exposures need to be reduced, in some cases, prevented altogether.

12. Chlorpyrifos has continued to be associated with acute pesticide poisonings, and data on chlorpyrifos poisonings collected and released by California's Department of Pesticide Regulation show that chlorpyrifos poisonings remain unacceptably high.

- a. The 2002¹ PANNA report showed that California's Pesticide Illness Surveillance Program ("PISP") had reported 156 chlorpyrifos poisoning cases between 1998 and 2000. We also noted that the reported poisonings likely represented only the tip of the iceberg, as many, probably most cases go unreported for myriad reasons including lack of familiarity among workers, residents, and physicians with signs and symptoms of pesticide-related illnesses and/or fear of retaliation among workers for reporting job-related incidents. We also pointed out that about half of all drift cases occurred when investigations determined that there had been no violations of pesticide use or worker safety regulations. In other words, the results demonstrated that the regulations themselves were inadequate to protect workers, and others, from pesticide exposure and associated poisonings.
- b. More recent PISP data suggest that poisonings by agricultural use of chlorpyrifos continue albeit at apparently lower rates.
- c. While most PISP cases are reported for workers, reports of direct acute poisonings among children exposed at school are not uncommon, with 34 cases reported (for all pesticides) between 2008 and 2011. The PISP reports of chlorpyrifos cases among workers in that time period totaled 62 with 49 attributed to drift exposure. There is a lag period of at least two or three years between incident and public reporting of PISP data, so while we believe incidents continue to occur these are the most up-to-date data available.

¹ Reeves, M., A. Katten and M. Guzmán, *Fields of Poison 2002: California farmworkers and pesticides*, Pesticide Action Network (2002).

- d. A recent report of agricultural pesticides used near California schools showed that chlorpyrifos was the 8th most common highly hazardous pesticide applied within ¼ miles of public schools.²

PANNA'S ACTIVITIES TO PROTECT CHILDREN AND COMMUNITIES FROM CHLORPYRIFOS

13. In addition to acute poisoning data, a continuously growing body of data demonstrates that both workers and consumers, including children, are regularly exposed to chlorpyrifos and other organophosphate pesticides. To complement these data, PANNA has conducted numerous field studies in California's Central Valley and elsewhere documenting the presence of chlorpyrifos (including at levels exceeding EPA's level of concern) in the air in communities located near citrus orchards where use of the pesticide is common during the summer months.

14. In 2003 PAN created the Drift Catcher, a simple air monitoring device designed to be used by trained lay people concerned about the presence of pesticides in the air in their communities. Modeled after similar devices used by government agencies, the collected samples are shipped to analytical laboratories for analysis. The community members then use the resulting data in support of public policy campaigns designed to win more protective public health policies. One good example was the use of Drift Catcher data, collected near homes in California's Tulare County, to successfully pass a 2008 ordinance requiring a one-quarter mile buffer zone (no spray area) around schools in session, occupied farm labor camps and residential areas. The buffer zone rule prohibits aerial applications of restricted use pesticides, including chlorpyrifos.

² California Environmental Health Tracking Program, *Agricultural Pesticide Use Near Public Schools in California* (2014).

15. PANNA's primary partner in both air monitoring (aka drift-catching) for chlorpyrifos was our member and long-time close partner El Quinto Sol de America (EQS) located in the town of Lindsay in California's Central Valley. Air monitoring in 2004 and 2005 showed levels of concern near participants' homes. In 2006, I worked with EQS to repeat air monitoring and found that 30% of the air samples showed levels of chlorpyrifos above the level considered safe, by US EPA, for a one-year-old child; one site had two results about 10 times the "safe" level.

16. In 2006, we added a biomonitoring component to the Lindsay study. In addition to levels of concern in the air near participants' homes, we found that all but one of the 12 biomonitoring participants (8 women and 4 men) had levels of chlorpyrifos in their urine above the "acceptable" level for pregnant and nursing women. One of the participants was a young nursing mother who lived with her family directly across the street from the Lindsay elementary school. In 2009, we conducted another chlorpyrifos air monitoring and biomonitoring study near Lindsay. Though air levels remained below levels of concern, 14 of 20 children or women of childbearing age (15-44) had levels of the chlorpyrifos metabolite TCPy in their urine above the Population Adjusted reference dose – or "safety" level of 30 ng/kg/day.

17. Our members who participated in both the air and biomonitoring studies are looking to PANNA to help them eliminate this avoidable source of contamination in their communities and in their bodies.

18. Along with Californians for Pesticide Reform (CPR), of which PAN is a founding member, and CPR partner groups, PANNA has engaged in air monitoring efforts in the towns of Lompoc and Parlier. These air monitoring efforts in turn led to the establishment of California's Department of Pesticide Regulations' (DPR) comprehensive Air Monitoring Network (AMN)

program one focus of which is the use of organophosphate (OP) pesticides including chlorpyrifos. Lindsay, CA is one of the four OP-focused monitoring sites (four other sites were selected for their high use of highly hazardous fumigant pesticides). PANNA, together with our CPR partners, has recently provided detailed comments to DPR on its 2016 monitoring report focusing on both monitoring protocols and, most importantly, DPR's interpretation and presentation of the monitoring results. Our comments noted that US EPA's revised risk assessment for chlorpyrifos reviewed DPR's AMN data and found that levels exceeded the levels of concern to protect against neurodevelopmental impacts at one of the monitoring sites. At that site, the highest 4-week rolling average for chlorpyrifos was 39.4 ng/m³ which is more than 18 times higher than the level of concern for pregnant women (2.1 ng/m³) set last year by USEPA scientists to protect against neurodevelopmental harm.

(http://www.cdpr.ca.gov/docs/emon/airinit/air_monitoring_plan_2017.pdf)

19. Organophosphate pesticides pose a high risk to people, and especially to fetuses, infants, and young children. EPA's actions to date demonstrate a double standard that results in unacceptable neglect of rural and farm children while suburban and urban children receive some necessary protections against exposure to chlorpyrifos. In 2000, EPA took effective measures to cancel almost all residential uses of organophosphate pesticides, which has resulted in significant and measurable reduction in poisonings to children from roach baits, residential foggers or "bug bombs," and other homeowner uses. These protections, while necessary, do not address dangerous forms of exposure to chlorpyrifos and other organophosphate pesticides from spray drift and volatilization drift, which primarily affects children living in rural and farming communities. Often, the children affected are the children of farmworkers, meaning that the harm EPA allows falls disproportionately on children in low-income and minority communities.

Any continued poisonings or permanent neurological harm to children is unacceptable. This double standard is especially alarming because of the disproportionate nature of the harm on already overburdened communities. Rural and farm children should be accorded the same protections as other children from this dangerous category of pesticides.

20. When EPA re-registered chlorpyrifos and the other organophosphates in 2006, it ignored exposures to children's and bystanders from pesticide drift. Ever since, we have advocated for EPA to consider drift among the aggregate exposures children face.

21. In 2007, we filed jointly with Natural Resources Defense Council a petition to ban all food uses of chlorpyrifos. The petition compiled the available data on drift and chlorpyrifos exposures.

22. In 2009, PANNA joined other farmworker and health advocates in petitioning EPA to protect children from pesticide drift. Pesticides in the Air – Kids At Risk: Petition to EPA to Protect Children from Pesticide Drift (Oct. 13, 2009) (the "Kids Petition"). The Kids Petition presented evidence of pesticide drift and argued that EPA had violated its legal obligation to protect children against all aggregate exposures, including those from pesticide drift.

23. In 2011, EPA released a preliminary human health risk assessment for chlorpyrifos, which acknowledges the need to address spray drift and volatilization drift and that studies show widespread effects resulting from chlorpyrifos exposure. PANNA filed comments on this assessment providing additional evidence and showing why EPA's assessment understates the risks to children from chlorpyrifos and a subsequent set of comments on EPA's volatilization assessment. Our comments are in www.regulations.gov at EPA-HQ-OPP-2008-0850-0098 and EPA-HQ-OPP-2015-0653-0165.

24. In its 2014 response to the Kids Petition, EPA acknowledged its legal obligation to address pesticide drift as an aggregate exposure under the Food Quality Protection Act, but indicated it would do so in its pesticide specific review of each pesticide. Agency Response to Pesticides in the Air – Kids At Risk: Petition to EPA to Protect Children from Pesticide Drift (Mar. 31, 2014), available at www.regulations.gov at EPA-HQ-OPP-2009-0825-0084.

25. After acknowledging its obligation to protect children from pesticide drift, EPA found that drift was reaching schools, homes, and other places children gather in toxic amounts, which led to the imposition of the first no-spray buffers for chlorpyrifos in 2012. EPA, Chlorpyrifos Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures at 7 & Appendix C (July 13, 2012), *available at* <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0105>. We have argued in public comments that these buffers are too small because they ignore volatilization and inhalation exposures. Our concerns have been substantiated.

26. In August 2017, the California Department of Pesticide Regulation released a draft evaluation of chlorpyrifos as a toxic air contaminant, which finds drift in toxic amounts at far greater distances from chlorpyrifos spraying, *i.e.*, EPA's buffers are far too small to protect children. http://www.cdpr.ca.gov/docs/risk/rcd/chlorpyrifos_draft_evaluation_2017.pdf, at 15-17.

27. On May 5, 2017, chlorpyrifos traveled one-half mile from a farm, sickening dozens of people. The Kern County Department of Agriculture and Measurement Standards found that chlorpyrifos drifted one-half mile from a farm. An applicator implicated in this drift incident was assessed penalties of more than \$30,000. The following month, 18 farmworkers

were sent to the hospital. An August incident, also in Kern County, is still under investigation but identified chlorpyrifos as one of the two pesticides sickening 70 farmworkers.

<https://www.panna.org/sites/default/files/Copus-Road%20Incident-May-Press%20Release.pdf>.

Here's a blog on the May 5 incident: <http://www.panna.org/blog/why-cant-california-regulators-stop-pesticide-drift>.

28. PANNA conducted a detailed analysis of chlorpyrifos body burden data from the Center for Disease Control biannual NHANES study. The 2004 report, "Chemical Trespass: Pesticides in our bodies and corporate accountability" showed that many U.S. residents carry toxic pesticides in their bodies above government assessed "acceptable" levels. Chronic exposure to chlorpyrifos metabolite, was furthest above the government safety threshold, with average levels for the different age groups three to 4.6 times what agencies at that time considered "acceptable" for chronic exposure of vulnerable populations (e.g. women, children and the elderly). As CDC noted in the 2003 release of the data, young children carry particularly high body burdens—nearly twice that of adults—of a metabolite specific to chlorpyrifos. A 2010 update study by the CDC reported that while exposure levels of four target chemicals declined, exposure to chlorpyrifos increased 10.8%

(https://www.cdc.gov/nchs/data/hpdata2010/hp2010_final_review_focus_area_08.pdf)

29. PANNA has engaged in concerted advocacy to obtain a nationwide ban on chlorpyrifos, including through the 2007 petition and a series of unreasonable delay cases seeking to compel EPA to act on that petition. Because EPA has delayed taking action, we have also devoted significant resources to advocacy in California to obtain restrictions and ultimately a ban on chlorpyrifos use in California. We have provided detailed technical comments on proposals and reviews of chlorpyrifos by California authorities and regulators; analyzed

California pesticide poisoning data; conducted air monitoring and biomonitoring of chlorpyrifos in California communities and tracked California monitoring; tracked and advocated for restrictions to prevent exposures of children at schools; and participated in hearings and proceedings on whether chlorpyrifos will be listed as a toxic air contaminant and as a reproductive or developmental toxicant under California's Proposition 65. PANNA partners and members of the statewide coalition Californians for Pesticide Reform (of which PANNA is an active, founding member) have devoted staff and funds for a concerted advocacy campaign to ban chlorpyrifos in California. If EPA had done its job and revoked all food tolerances in a timely manner, PANNA would no longer need to devote its resources to this campaign.

30. In addition to the work I've done for the past 21 years at PANNA on behalf of pesticide-exposed PANNA members, I also have personal experiences that influenced my decision to directly engage with PANNA's work. In the 10 years prior to coming to PANNA, part of my graduate student and post-doc research in Costa Rica involved the use of Lorsban (chlorpyrifos) on the corn plants with which I was conducting my research. In fact, I directly applied granules of Lorsban by hand, to the developing tassels of corn plants. Though I was sufficiently careful to protect my skin from exposure, at no point did anyone with whom I was working, including more experienced agronomists or researchers, ever mention the potential dangers of exposure. As chlorpyrifos is relatively rapidly flushed from the body, I have no way to know if, at that time, I experienced exposure at levels of concern.

31. More recently, while conducting the biomonitoring study in Tulare County in the summer of 2005, I was driving near orange orchards and witnessed a nighttime pesticide application. Though there was no indication of what pesticide was being applied, there was a very good chance that it was chlorpyrifos. In response, I collected my urine sample in the same

way we were collecting study participants' samples and sent it along with the other samples to the analytical laboratory. My resulting level of the chlorpyrifos metabolite TCPy was 4.26 µg/L which is substantially above the 1.5 µg/L average level of adults as reported by CDC in its Third National Report on Human Exposure to Environmental Chemicals, July 2005. So therefore, I experienced an unacceptable chlorpyrifos exposure, though my exposure was only on one occasion unlike many of the PANNA partners and members on whose behalf I have dedicated the past 21 years of work at PANNA.

32. Because of EPA's failure to ban chlorpyrifos, PANNA members and their children are still being exposed to unsafe levels of chlorpyrifos and will continue to be as long as the chlorpyrifos registrations and food tolerances challenged in the petition remain in effect.

33. By denying the 2007 Petition in March 2017 and putting off a decision on whether chlorpyrifos must be banned for what could be five more years, EPA has harmed and is harming PANNA and its members.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 22 day of January, 2018, at Berkeley, CA.


MARGARET REEVES

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,Respondents.

Declaration of Martha Moriarty

I, MARTHA MORIARTY, declare and state as follows:

1. I am the Executive Director of the Learning Disabilities Association of America's ("LDAA") Minnesota affiliate, Learning Disabilities Association of Minnesota ("LDA Minnesota"). I have worked with LDA Minnesota since 2001 and was hired as the Executive Director in 2013. I have been a member of LDAA since LDA Minnesota became an affiliate organization in 2002. LDA Minnesota has been working with families impacted by learning disabilities for over 50 years.
2. As the leader of LDA Minnesota, I see families from across the state who contact us for help or who come to our trainings about learning disabilities. Minnesota is a big agricultural state, and there are many families from rural areas who are facing severe challenges

with their children's ability to access support and appropriate special education services for their learning disabilities. Many families call us to help find qualified tutors to help their children outside of school services, LDA has begun offering virtual online tutoring to fill the gaps in rural areas where there are not trained tutors for learning disabilities. There is a lack of qualified special education teachers in our rural schools, including in areas where my nephews attend school. Special education teachers are spread thin and often must share classrooms, or in some schools, general education teachers can obtain a waiver to teach special education students due to the shortage of properly trained and certified educators. As incidence of learning disabilities increase, there is the possibility for a real education crisis, especially in our rural communities. I support LDAA's efforts to seek a nationwide ban on chlorpyrifos because we want to avoid such a crisis and we want healthy brain development in children.

3. I am aware that chlorpyrifos has terrible immediate side effects on people that are exposed to it, and that it effects healthy brain development in children. These kinds of long-term impacts on brain development affect a child's ability to reach his or her full potential, and the costs to society and to families are enormous. For families, it can impact jobs, educational opportunities, and long-term health care needs. For society in general, harm to the developing brains of children also negatively impacts systems meant to support people, including health care, social services, and the educational system. The economic impact is much wider than most people think about when you consider the long-term costs of all the things needed to support a person with learning disabilities. For example, the cost of educating a child through special education is \$16,000, over double the cost of educating a student in general education (NEA, 2004 IDEA Reauthorization).

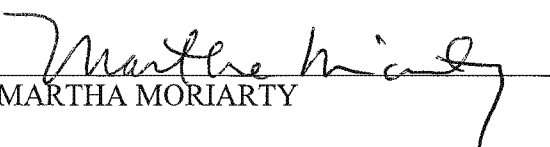
4. The work that I do with LDA Minnesota is not just a job, it is also personal. I have nieces and nephews in both my family and my husband's family who have learning disabilities and attention-deficit/hyperactivity disorder ("ADHD"). They are now in middle and high school, and I have supported my siblings and in-laws with the challenges they face in raising children with learning disabilities. Being a parent of a child with a disability can be challenging throughout childhood, but particularly as they begin entering adulthood and making transitions from school to college and career are causing my relatives parents stress and concern for their child's future independence. I worry about my extended family's continued exposure to pesticides, including chlorpyrifos, because they live in agricultural areas. I don't think it is a coincidence that my family members who have more exposures to pesticides due to where they live are the ones with learning disabilities and ADHD.

5. My immediate family and I enjoy camping and other outdoor activities, and we travel all over the state for recreation. One time when we were camping in rural Minnesota, we saw a plane dropping pesticides on a nearby field and we were alarmed by our potential exposure and wondered if we should be camping in that area. I would feel safer for myself and my family if I knew that neurotoxic pesticides like chlorpyrifos were banned so we are not at risk of exposure when we are visiting rural areas in our home state.

6. I do the work that I do with LDAA and LDA Minnesota because I want children to grow up in a healthy environment, free from neurological harm from toxic pesticides like chlorpyrifos, and with the ability to reach their full potential.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 19 day of January, 2018, in Minneapolis, Minnesota.


MARTHA MORIARTY

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Maureen Swanson

I, MAUREEN SWANSON, declare and state as follows:

1. I am currently the Director of the Healthy Children Project at the Learning Disabilities Association of America (LDA).
2. I have a Masters in Public Administration from the School of Public and Environmental Affairs at Indiana University, with a concentration in environmental policy. Prior to my tenure at LDA, I was a senior policy analyst at the Minnesota Office of Environmental Assistance, now part of the Minnesota Pollution Control Agency.
3. I am a co-author of two peer-reviewed articles on how toxic chemical exposures affect children's brain development:

- Bennett D, Bellinger DC, Birnbaum LS, et al; Project TENDR (Targeting Environmental Neuro-Developmental Risks: the TENDR Consensus Statement. Environ Health Perspect. 2016;124(7):A118-A122; and
- Swanson, Maureen and Hepp, Nancy. Protecting Brain Development: How Toxic Chemical Exposures Interact with Nutrition and Genetics to Put Children at Risk. Journal of Amer. Speech-Language-Hearing Assoc. SIG 16 Perspectives on School-Based Issues. Aug 2012;13:54-49;

And a contributing author to:

- Bellinger D, Chen A and Lanphear B. Establishing and Achieving National Goals for Preventing Lead Toxicity and Exposure in Children. JAMA Pediatrics. May 2017;E1-E2
Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

4. As the Director of LDA's Healthy Children Project, I work to raise awareness of environmental factors, particularly toxic chemicals, that may interfere with healthy brain development and contribute to learning, attention and behavior disorders, with a focus on the fetus, infants and young children, who are especially vulnerable to harm from toxic chemical exposures. I work in partnership with other health and disabilities organizations, health-affected individuals, environmental and environmental justice groups, health professionals and scientists to translate the scientific evidence into effective changes in policies and practices to reduce chemical exposures linked to disease and disabilities.

5. I also am co-founder and co-director of Project TENDR (Targeting Environmental Neuro-Developmental Risks). TENDR is an alliance of more than 50 leading scientists, health professionals, and children's health advocates, who in July 2016 published a consensus statement as a national call to reduce widespread exposures to chemicals that interfere with fetal and children's brain development. In the statement, the TENDR experts named prime examples of toxic chemicals that are increasing children's

risks for learning, behavioral or intellectual impairment, as well as specific neurodevelopmental disorders such as ADHD, learning disabilities and autism. These exemplar chemicals include organophosphate pesticides, a class of pesticides that includes chlorpyrifos.

6. According to the U.S. Centers for Disease Control and Prevention, the prevalence of learning and developmental disabilities in American children increased 17% from 1997 to 2008, meaning that 1.8 million more American children had a learning or developmental disability in 2006-2008 compared to a decade earlier. Based on the CDC's analysis, published in 2011, one in six children in the United States has a reported learning or developmental disability.

7. Learning disabilities cover a range of brain-based disorders and difficulties with learning and processing information, with varying degrees of severity. These disorders involve problems with auditory and visual perception, sequencing and organization, memory, expressive language and fine and gross motor skills. Learning disabilities can include short attention span, difficulty following directions, inability to discriminate among letters, numbers or sounds, difficulty with reading and writing or math, and problems with coordination, and sensory difficulties. Learning disabilities can co-occur with attention and behavior disorders.

8. Learning and developmental disabilities persist – with lasting impacts on children, families and society. On average, it costs twice as much to educate a child with a learning or developmental disability as to educate a child without a disability. Adolescents with learning disabilities are much more likely to drop out of high school, have problems with substance abuse, and wind up in the juvenile justice system. By

conservative estimates, at least one third of children in the juvenile justice system in America have one or multiple learning or behavior disorders. High school graduates with learning disabilities are much more likely to be unemployed and have trouble keeping a job.

9. In working on toxic chemical issues related to problems with brain development, LDA and partner organizations address the broad range of learning and developmental disabilities for which toxic chemical exposures can be contributing factors, including ADHD, intellectual impairments, learning disabilities and autism spectrum disorder.

10. Based on the extensive and mounting toxicological and epidemiological evidence, and in light of widespread exposures, particularly to pregnant women and children, there is now scientific agreement that toxic chemicals, including organophosphate pesticides, are harming brain development, and that even low-level exposures can increase children's risks for learning, behavioral or intellectual disorders. In utero and during early childhood, there are critical windows of development when even tiny doses of toxic chemicals can do lasting harm.

11. Chlorpyrifos, measured by its specific metabolite, TCPy, was detected in more than 91% of women of childbearing age in the CDC's national biomonitoring data (NHANES). According to the CDC, this high percentage of detectable concentrations of chlorpyrifos implies ubiquitous exposure, probably primarily through the food chain. In recent years, multiple studies of pregnant women have shown that chlorpyrifos is present in pregnant women, in umbilical cord blood and in children.

12. The National Academy of Sciences estimates that environmental factors, including toxic chemicals, cause or contribute to at least a quarter of learning and developmental disabilities in American children. Although learning and developmental disabilities are complex disorders with multiple causes—genetic, social, and environmental—the contribution of toxic chemicals to these disorders is entirely preventable.

13. I have worked as the Director of the Healthy Children Project since December 2006, and am familiar with LDA's policies, practices, membership, and programs. The Learning Disabilities Association of America is a national non-profit membership organization. LDA members are people with learning disabilities, their parents and family members, educators including teachers, professors and school administrators, medical professionals including psychiatrists, psychologists, physicians and nurses; therapists and other service providers, and lawyers and specialists in the areas of education policy, human rights and disability policy and law.

14. Founded in 1964, LDA is headquartered in Pittsburgh, Pennsylvania, with state and local chapters throughout the country. It provides support, information and advocacy on behalf of individuals with learning disabilities. Members of LDA join the organization by paying annual dues. Members elect the board, which is the presiding body that votes on actions and policies. Board members are members of LDA. The general membership chooses delegates from each state who elect the Board members at the annual Assembly of Delegates meeting.

15. LDA established the Healthy Children Project (HCP) in 2002 to raise awareness of environmental factors, particularly toxic chemicals, linked to problems with

brain development and function, and to reduce and prevent toxic chemical exposures, especially among pregnant women, infants and children, through educating and advocating for changes in products, practices and policies. In 2005, LDA's Board of Directors, elected by LDA members across the country, added "*and to reduce the incidence of learning disabilities in future generations*" to LDA's mission statement to reflect LDA's commitment to the goal of protecting children's brain development from toxic threats. LDA's mission is thus "to create opportunities for success for all individuals affected by learning disabilities, and to reduce the incidence of learning disabilities in future generations."

16. LDA annually secures funding to prioritize, maintain and expand initiatives to ensure its members and the public are kept informed of the latest scientific research on toxic chemicals and health, and made aware of ways to help reduce their families' exposures to toxic chemicals. LDA regularly disseminates the results of scientific research on environmental factors putting children at higher risk for learning disabilities, along with information on ways to reduce toxic chemical exposures, through social media, action alerts, factsheets, newsletter articles and presentations and workshops at LDA's national annual conference, and at conferences and meetings throughout the country.

17. LDA convenes meetings of scientists, health professionals, education professionals and children's health advocates to learn and share the latest research findings on chemicals and brain development, and to plan and implement strategies to protect children from toxic chemical exposures.

18. LDA strives to ensure that the concerns and interests of its membership are represented in chemical policy decisions that affect children's health and neurological development. LDA holds Congressional briefings, provides written and oral testimony at hearings and public meetings, submits comments to federal and state legislative dockets, meets with policymakers to provide expertise on toxic chemicals and learning disabilities, writes sign-on letters and conducts outreach to partner learning and developmental disability groups, along with scientists and health professionals, to write letters to policymakers, holds press conferences and writes opinion articles and letters to the editor.

19. LDA also provides opportunities for members across the country to share their perspectives with decision makers on chemical safety issues, through action alerts that generate phone calls and e-mails, assisting with letters to the editor, drafting and circulating letters for state LDA leaders to sign, etc.

20. To better engage and serve its membership on environmental health issues, I along with LDA's Affiliate Coordinator created and coordinate a network involving twenty LDA state affiliate offices who are engaged on a consistent, ongoing basis in advocacy for safer chemical policies with policymakers at the state and federal levels. Through monthly conference calls, regular on-line communication and annual training workshops, we equip LDA state affiliate leaders – who are LDA members, both paid and volunteer – to raise awareness and disseminate information on toxic chemicals and brain development. LDA state members conduct outreach and give presentations to other non-profit groups such as state chapters of The Arc or Autism Society, to schools and child care centers, including Head Start programs, and to parent and health care provider groups, such as PTO and nurse's associations. This network of state LDA

leaders, along with the national office, engages the wider membership and the public through action alerts, social media, presentations at state and national conferences, etc., to disseminate information on toxic chemical threats to healthy brain development, and ways to reduce prenatal and children's exposures to toxic chemicals.

21. After EPA Administrator Pruitt refuted long-established scientific evidence showing low levels of chlorpyrifos harming children's brain development, and decided not to ban chlorpyrifos to protect children's health, LDA took action at the state and federal levels, alerting its membership, the Board, and state affiliate leaders through conference calls, an action alert and an e-newsletter article. Last summer, I, along with five LDA advocates from states where chlorpyrifos is more heavily used in agriculture, traveled to Washington D.C. for two days of meetings with Congressional offices to share our concerns with EPA's decision.

22. I was invited to give remarks on behalf of LDA and Project TENDR at Senator Udall's press conference introducing his bill to ban chlorpyrifos. My remarks focused on the scientific consensus that chlorpyrifos changes babies' brains, and contributes to the incidence of learning, behavior and intellectual disorders. LDA widely shared the video of my remarks through social media.

23. As co-director of Project TENDR, I coordinated the drafting and sign-on of two separate sets of comments to EPA regarding banning chlorpyrifos. The first comment letter, "Comments to EPA from Environmental Health Scientists and Healthcare Professionals in Support of EPA's Proposal to Revoke Chlorpyrifos Food Residue Tolerances," was submitted in January 2016. The second comment letter, "Comments to EPA from Environmental Health Scientists and Healthcare Professionals

in support of EPA's 2016 Revised Human Health Risk Assessment and the 2015 Proposed Tolerance Revocation for Chlorpyrifos," was submitted to the federal register in January 2017. Both comment letters were signed by dozens of scientists and healthcare professionals.

24. I also am assisting TENDR members who are providing testimony in support of state bills to ban chlorpyrifos. Currently, I have convened a small group of experts who are drafting and providing testimony in support of a bill in Maryland.

25. Because more individuals are likely to be at higher risk for learning disabilities due to EPA's decision, including children born in subsequent years, LDA will be forced to expend more time and money to provide them with information and assistance. Indirectly, thousands of schools and educators across the country who rely on LDA and are LDA members, along with their communities and the families they serve, also will bear increased costs to assist and educate children with learning disabilities.

26. LDA members are being harmed by the EPA decision not to ban chlorpyrifos last year because they are being exposed to this pesticide in their food, in their drinking water, and when it drifts to their homes, day care centers, and schools from the fields where it is sprayed.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true

Executed this 19th day of January, 2018, at Pittsburgh, Pennsylvania.



MAUREEN SWANSON

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Mónica Ramírez

I, MONICA RAMIREZ, declare and state as follows:

1. I am the Deputy Director of the Labor Council for Latin American Advancement (LCLAA), and I have held this position for six months. I am submitting this declaration to describe the interests in this litigation of LCLAA members in obtaining a nationwide ban on chlorpyrifos.
2. I currently live in Chevy Chase, Maryland.
3. I grew up in a rural community in Ohio that has a vibrant agricultural economy where farmers regularly apply pesticides and other chemicals to the crops, which poses health risks to the workers who live on the premises and in the nearby area.

4. Many of my family members worked in the agricultural fields in Ohio and other states around the country for many years as migrant farm workers.

5. I have been a member of LCLAA since 2016.

6. In my capacity as Deputy Director of LCLAA, I support the executive director with the general administration of the organization. I also support the programmatic work of the organization, such as planning events, conferences, worker delegations, briefings and meetings related to specific issues that impact workers, such as pesticides exposure, environmental protection standards, equal pay, sexual harassment and other issues. During my time with LCLAA, I have helped to plan and support LCLAA member delegations to meet with members of Congress related to pesticides exposure. I have also met with staff members from Congressional offices to discuss our concerns related to the harmful impact of pesticides on farmworker families and the nearby area residents who are exposed to drift, not to mention consumers who are at risk of long term health consequences due to consumption of products that have been grown with organophosphate pesticides like chlorpyrifos.

7. Prior to my role at LCLAA, I have been an advocate on behalf of farmworkers, specifically farmworker women, for over two decades, including serving as an attorney for farmworkers in different types of cases related to promoting their rights and helping them access justice. I have represented migrant farmworker women in employment litigation, as well as administrative complaints specifically related to pesticides exposure. In addition, I have conducted educational trainings and outreach to migrant farmworker women and their families related to the health consequences of pesticides exposure, how to identify whether an individual has been exposed to pesticides and how to limit introducing pesticides into a workers' home, among other things.

8. As an advocate and activist, I have created several major projects and initiatives related to advancing and protecting the rights of farmworker women. Among these, in 2011, I helped to co-found Alianza Nacional de Campesinas (The National Farmworker Women's Alliance), which formally launched in 2012. I currently serve as the President of the Board of Alianza.

9. Alianza de Campesinas is an organization that is comprised of women who currently and formerly worked as migrant farmworkers, in addition to individuals who come from farmworker families. The organizational priorities have been established by farmworker women for farmworker women and, since its establishment in 2012, pesticides has been one of the top advocacy priorities.

10. Alianza has worked to address concerns related to the devastating consequences of pesticide exposure, application and use on farmworker women, including birth defects in children, miscarriage, neurological deficiencies and harm, headaches, nausea and other health consequences, by conducting public education events with community members, hosting our a public awareness art activism project "moralitos" each February, which encourages community members to design handkerchiefs with messages related to ending the use of pesticides and providing needed care to community members who have been exposed, and engaging in advocacy with political leaders to educate them about the health consequences to farmworkers and other communities due to the use of pesticides on the produce that farmworkers grow and harvest, as well as food that consumers eat and fields that community members live near that present the danger of pesticide drift to individuals in the area surrounding the agricultural fields.

11. I am personally concerned with my own family's health related to exposure to chemicals. Several of my family members who worked in the agricultural fields and individuals

who lived for years in agricultural communities, including the one where I was raised, have died from cancer. While it is difficult to know whether their health challenges were related to their exposure to pesticides, knowing the impact of pesticides on individuals, I worry that these illnesses may have stemmed from exposure to pesticides.

12. I've learned that in Ohio, chlorpyrifos is used in corn, soybeans, alfalfa, vegetables, fruit, orchards and other crops. As a teenager, I worked for a very short period picking cucumbers in Ohio. I don't know if I was exposed to chlorpyrifos, but I worry that I might have been exposed to pesticides while I worked in the fields. I am also concerned that I could be at risk for health consequences because I have spent years near and around agricultural fields because of where I have lived, not to mention because of my work which has put me in frequent contact with agricultural fields where pesticides were likely applied.

13. As a mother to a four-year-old son, I have concerns about the produce that he consumes and whether he will experience any negative health effects where pesticides have been used on the fruits and vegetables that he eats, particularly where these chemicals might have leached into the produce or where residue remains on the food that he eats. In particular, I am deeply concerned about my son's brain and body development, if he has been consuming products with residues of chlorpyrifos in food and drinking water.

13. I am aware that studies show associations between early life exposure to chlorpyrifos and decreased cognitive function and behavioral problems. I am also aware that chlorpyrifos is used in many fruits and vegetables that children eat. This is particularly troublesome since relative to adults, kids consume more fruits and vegetables, and drink more water and juice.

14. As the child of farmworkers and an advocate for farmworker women and their families, I am concerned about the exposure of children to pesticides in agriculture and beyond. It's estimated that there are approximately 500,000 children that labor in agriculture and exposure to agricultural chemicals at an early age can cause irreversible harm.

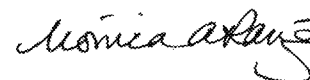
15. In addition to occupational exposure to pesticides for the children, women and men that work in agriculture, take-home exposure puts farmworker families at risk since farmworkers bring chemical residues on their bodies and clothes. If farmworkers are not adequately trained about the dangers of take-home exposure for children, pregnant women and others in their family, they may not know that they should change their clothes before going into the house or embracing their children.

16. Due to my experience working with farmworker communities and what we know about neurotoxic chlorpyrifos, I was appalled to learn that EPA Administrator Scott Pruitt is ignoring the science showing that chlorpyrifos is harmful to children and farmworkers and is refusing to ban chlorpyrifos. This decision leaves farmworker women, individuals living in rural communities and all consumers exposed to a chemical that does not belong in our food or our communities. Given the neurological impact resulting from the use of chlorpyrifos, its use stands to have economic and monetary consequences. Workers cannot work to their full potential if they get sick from pesticides that are applied while they are working or in the vicinity where they live. This, thus, results in a negative consequence for our economy. In addition, healthcare costs that are incurred, some of which must be paid for through public health programs, result in monetary harm consequences that could be avoided. These consequences are immediate, long-lasting and wholly preventable.

17. In July 2017, I joined a delegation of LCLAA members who came to Washington, DC to urge the Senate to support a bill that would ban food uses of chlorpyrifos.

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct, to the best of my knowledge, information, and belief.

Executed this 19th day of January 2018, in Washington, DC.

A handwritten signature in cursive script, appearing to read "Mónica Ramírez", written in black ink.

Mónica Ramírez

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Ofelia Aguilar

I, OFELIA AGUILAR declare and state as follows:

1. I have lived in the United States since 1992. I live in Homestead, Florida, in an agricultural area. I have always worked hard to earn a living for my family and I worked as a farmworker for over twenty years. I have also been a member of the Farmworker Association of Florida (FWAF) for almost two decades.
2. I have worked with the Association since they started doing trainings about pesticides and workers' rights. I participate in the activities as a volunteer. I invite new members to be informed just like me. If there is abuse, the Association helps us understand the process and how to file claims. They also inform us how to take care of our health and where workers can turn to if they do not have health insurance.

3. As a farmworker, exposure to pesticides happens frequently. I worked on a farm for almost two years and in the last three months before the pesticide poisoning incident I experienced there, I was assigned to work in an area where pesticides were being applied near me every day. This farm had a plant and flower nursery, where the plants are kept in both open-air and enclosed areas. It was the season of the Mandevilla plant and I was assigned to work in that area. Mandevilla is a plant with flowers of various colors, and they were spraying them while other workers were tying the plant to some wooden sticks, which is what we do so that as the plant grows; the plant wraps around the sticks and it helps it take form. We would work in groups of 15-20 women that prepared the plants, and in our group there was a supervisor who would come once or twice a day to check on the work and then would leave. The pesticide application was happening very close to me, to give you a sense of how close it was, it's as if I was standing on the driveway of your house and the pesticide applicators were in the yard. The applicators always sprayed the plants near us. On a daily basis, we would comment to one another that the smell of the pesticides was unbearable. The pesticides are applied even on windy days. Although the odors were strong, we were afraid to complain for fear of being fired. The supervisors would tell us that whatever was being applied would not harm us.

4. After spending three months working in the Mandevilla area, I began to feel sick. I felt dizzy, with a strong headache, and my eyes burned a lot. I told my supervisor that I didn't feel well and he told me not to worry about it. In the last week of that month, I summoned my courage to tell my immediate supervisor that I was feeling worse and needed help. His reaction only made things worse. He told me that I felt sick because I was old. At the time of the incident, I was only 43 years old. He also told me that he didn't have anything to give me to make me feel better and that if I wanted medicine, I had to get it myself. I asked the supervisor to take me to the doctor

and he told me that he was not going to stop working and leave his job to listen to my complaints. He told me that other people were not complaining, so there was no problem. However, I knew that other fellow workers were not feeling well either but they were afraid to say anything out of fear of being fired.

5. After that incident and with difficulty, I headed home. There was a driver that handles the van that transports the workers from the Mandevilla farm to the area where we park our cars and punch our time cards. The driver saw me and noticed that I was having difficulty getting into the van. My body was trembling, my head and throat really hurt and I could not speak clearly. He told me, "you have to ask for help. You have to complain because those people do the same with everyone." He was referring to putting people to work without caring if the work was making them sick.

6. That day, I arrived at my house with great difficulty. I did not go to the hospital because I was going through a very tough economic situation and I was afraid of having to pay a large bill for services. I could not eat dinner when I got home. I only drank water. The next day I woke up with a severe stomach ache. It took two days for my eyes to get better because they were very red. I felt nauseous for several days. Many months after the incident I could not eat with ease because my stomach would still hurt so much.

7. The evening of the incident, I called the Association to inform them about what had happened and they told me to go to their offices to document the incident because what the supervisor had done was not right.

8. The next day, when I returned to work, my supervisors were annoyed with me. They told me that I wouldn't be working in the area where I got sick. They separated me from my co-

workers and made me work by myself. At noon, I called the supervisor and asked him to give me a copy of the pesticide incident report because I needed it. I asked him to bring it to the area where I was working. He told me he wasn't going to stop doing his job and pretended not to know what I was talking about. When I insisted, he said that he did not have to write a report and that he was not going to give me anything because he claimed that I was a problematic person. He also said that he had asked for me to be assigned to work in another area where he did not have to deal with me.

9. That is why I turned to the Farmworker Association of Florida for help. Through the Association, I learned about my rights and they informed me that when pesticide poisoning occurs, the employer has to document the incident and report it.

10. I stopped working in the fields because my employer was retaliating against me, and my coworkers were told not to talk to me because I was a "bad influence." I was the only person that complained and I worry about all the workers who are exposed to really harmful pesticides but are afraid to speak out. Many people are just trying to make ends meet and they are afraid to complain for fear of losing their jobs. I had the Association to turn to for help, but what about other workers across the country that don't have organizations that can help them when pesticides are making them sick? I cannot pronounce chlorpyrifos but I've learned that it is used in many products in Florida, including fruits like citrus, vegetables and ornamental plants. I don't know if I was exposed to chlorpyrifos while I was working but I have learned that this chemical poisons many workers.

11. I worry about my family's exposure to pesticides because I have children and grandchildren, and I do not want them to go through the incident that I went through. I have seen children and young people working on the farms, in the vegetable fields and in the nurseries. I

worry that they are being exposed to pesticides. My youngest son is three years old, and I have three grandchildren, a four-year-old, a two-year-old and a three-month-old baby. I am worried that they will be exposed to some type of chemical that impacts their development. Pesticide poisoning is something horrible that I do not want anyone in my family or any human being to experience.

12. It is not fair that the administration is refusing to ban this chemical and is not considering the health of farmworkers and children. They are only considering the economic benefit and the profits of the corporations making these chemicals and they are forgetting about us, the people that are most exposed.

13. I worry that this chemical is in the food my family eats and the water we drink. I also worry about pesticide drift because we constantly experience it here. Where we live there are fields of beans, corn, cucumber, guava and tomato and when they apply pesticides, it is dispersed by the air and reaches our homes. You can feel it when the pesticides get inside your home, you can smell it and you feel uncomfortable. Now that I have the baby, when we see people spraying pesticides, we get in the car and drive away so we do not have to breath it. But the problem is when they spray at night –the smell enters the home and we cannot do anything about it.

14. To advocate for stronger protections for farmworker families and communities, I traveled to Washington, DC in July 2013. I have met with officials at the Environmental Protection Agency (EPA) and I spoke at a Congressional briefing on pesticides, urging for stronger protections from pesticide exposure. It's important that decision makers know that their policies affect people like me and my family, and many more. I hope that our voices will be heard and that this toxic chemical is banned to protect us all.

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct, to the best of my knowledge, information, and belief.

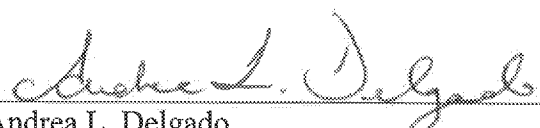
Executed this 19th day of January 2018, in Homestead, FL.

Ofelia Aguilar

Ofelia Aguilar

CERTIFICATE OF TRANSLATION

I, ANDREA L. DELGADO, pursuant to 28 U.S.C. § 1746, declare under penalty of perjury under the laws of the United States of America that I am fluent in the English and Spanish languages and that I truly and correctly translated the foregoing declaration to the best of my ability.



Andrea L. Delgado

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,Respondents.

DECLARATION OF RAMON RAMIREZ

I, RAMON RAMIREZ, declare and state as follows:

1. I am the President of Pineros y Campesinos Unidos del Noroeste (Northwest Treeplanters and Farmworkers United or “PCUN”). I have held this position since PCUN’s founding in 1985. Before becoming President of PCUN, I worked as a farmworker organizer.

2. Based in Woodburn, Oregon—the center of Oregon’s agricultural industry—PCUN is Oregon’s only farmworker union and the largest Latino organization in the state. Since its founding, PCUN has registered over 6,000 members, 98 percent of whom are immigrants from Mexico and Central America. Approximately one-third of PCUN’s members come from indigenous communities in the Mexican states of Oaxaca, Puebla, Guerrero, Michoacan, Nayarit,

Sinaloa, and Baja California. Most of these indigenous workers speak indigenous languages, such as Mixteco, Trique, or Zapoteco, but little to no English or Spanish.

3. PCUN's mission is to empower farmworkers to recognize and take action against systematic exploitation and all of its effects. To this end, PCUN is involved in community and workplace organizing on many levels. For example, PCUN's Collective Bargaining Committee negotiates and implements union contracts with local farms. Our Service Center provides members with support services such as translation, referrals to attorneys, and immigration assistance. Our Workplace Health program seeks to combat serious threats facing Oregon's farmworkers, including exposure to dangerous pesticides, a lack of education about safe pesticide use, sexual harassment, and workplace sexual assault. To educate and entertain our community while also raising political consciousness, PCUN operates Radio Movimiento, a community radio station with the slogan "La Voz del Pueblo" (The Voice of the People).

4. PCUN's members help to select the union's priorities by voting at annual meetings. As President, I am involved in coordinating all of PCUN's activities. Much of my time is devoted to lobbying Oregon's legislature and partnering with organizations across the country to protect farmworker rights. In June 2017, I traveled to Washington, D.C. to ask senators from the Pacific Northwest in support of a bill to ban food uses of chlorpyrifos.

5. Exposure to pesticides and other agricultural chemicals is a serious problem in our community. Many of PCUN's members have experienced the effects of exposure to pesticides. These symptoms include headaches, dizziness, fatigue, sleeplessness, nausea, and vomiting. In addition to pesticide exposure at work, many PCUN members live very close to areas where pesticides are applied. As a result, these members—along with their children—are threatened by exposure to dangerous pesticides even when they are not at work, because pesticides drift from

fields to their homes. Some farmworker housing is only a few feet from fields where pesticides are sprayed, and people can be exposed to pesticides even when they are indoors. This is especially true during the summer months when people have open windows, or fans and air conditioners bring in air from outside, and they receive no notification when pesticides will be sprayed near them.

6. I have experienced symptoms of pesticide poisoning after being exposed through spray drift. Around April 2004, I was standing near a field when a cloud of pesticides fell on me and the group I was with. I immediately began to feel itchy. My eyes watered. I became dizzy, nauseous, and thirsty. I reported this incident to the Oregon Occupational Safety and Health Administration.

7. I understand that the United States Environmental Protection Agency (“EPA”) found that people may be exposed to chlorpyrifos through their drinking water, and that people who live in agricultural areas may be at more risk of drinking water contamination. I also understand that EPA’s proposal to ban chlorpyrifos was based on unsafe drinking water exposures. I am also aware that the U.S. Department of Agriculture has detected unsafe levels of chlorpyrifos on fruits and vegetables. In addition to drift and work exposures, PCUN’s members and their families may also be exposed to this dangerous pesticide through the food they eat and the water they drink.

8. I know of two schools in Woodburn that are located very close to agricultural fields. On numerous occasions, I have seen pesticides being applied to those fields. PCUN’s members with children at these schools are afraid that their children will be exposed to pesticide drift while playing outside at recess. Having seen how close the pesticide spray comes to the

schools, I am also concerned about the safety of these children, especially with pesticides like chlorpyrifos that harm children's brains.

9. I am aware of EPA's findings that chlorpyrifos is a toxic chemical that is harmful to all people, and especially to children. I was disappointed when I learned that EPA Administrator Scott Pruitt acted against the findings and recommendations of EPA's own scientists and refused to ban chlorpyrifos. Following Administrator Pruitt's denial, PCUN joined the other petitioners in filing objections with EPA and filing this lawsuit on June 5, 2017.

10. PCUN has invested resources in educating farmworkers about the harms associated with chlorpyrifos exposure and campaigning to get this pesticide banned. Because EPA refused to ban the pesticide and is delaying acting on the objections, PCUN must expend additional time and resources on educating our members about chlorpyrifos and campaigning for a ban. I hope EPA responds to the objections and acts to ban chlorpyrifos. EPA's ongoing delay leaves us in a state of limbo, and leaves workers and their families at risk, which this lawsuit seeks to remedy.

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct, to the best of my knowledge, information, and belief.

Executed this 19th day of January, 2018.



Ramon Ramirez

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

DECLARATION OF SHARON BOLTON

DECLARATION OF SHARON BOLTON

I, SHARON BOLTON, declare and state as follows:

1. I have been a member of the Natural Resources Defense Council (NRDC) since 2009, and I support NRDC's efforts to compel the Environmental Protection Agency (EPA) to protect the public from hazardous chemicals.
2. I am 67 years old and I live in Tyler, Texas.
3. I have three children and three young grandchildren, all of whom reside in Tyler.
4. I am aware that organophosphate pesticides including chlorpyrifos are commonly applied to a variety of crops in the United States and represent a hazard to human health. I initially learned about the risks of pesticide exposure over forty years ago, and I am deeply concerned about the consequences of chlorpyrifos use to public health and the environment.
5. I am concerned about my and my family's exposure to chlorpyrifos and chemicals like it. I live near peach orchards, and I am worried that I may be exposed to chlorpyrifos and other organophosphate pesticides that are applied to those orchards. My children and grandchildren also live in this area, and I worry that exposure to these chemicals will adversely affect their health.
6. I have three young grandchildren, 4-year-old, an 8-year-old, and a 10-year-old. They frequently play outdoors, and I am concerned that exposure to chlorpyrifos and chemicals like it may adversely affect their health and development.
7. I am particularly worried about the hormone disrupting effects of chlorpyrifos. My niece resides in Elwood, Indiana, within twenty miles of many working farms. She experienced a hormone abnormality that required consistent medical treatment for the entirety of her childhood. I am concerned that exposure to chlorpyrifos and pesticides like it interfered with her hormone functions.
8. I am concerned about pesticide residues, including chlorpyrifos, on the fruit and vegetables that I consume. Because of this concern, I purchase organic produce whenever possible. Also, I do not use chlorpyrifos or chemicals like it at home. But I am concerned about exposure that is not within my control.
9. I drink tap water and believe that it should be free of hazardous concentrations of chlorpyrifos and other toxic chemicals. I am concerned that my tap water could be affected by chlorpyrifos.

10. I am worried about chronic effects of long-term exposure to chlorpyrifos and pesticides like it for my children and me. I was raised in Muncie, Indiana, and resided there until I was thirty years old. During that time, I lived in an agricultural area on property neighboring working farms. I am concerned that exposure to chlorpyrifos and pesticides like it during that time caused damage to my health. I lived in Indiana during my pregnancies and after the birth of my children, and I worry that my exposure to these chemicals adversely affected their health. In addition, I regularly observed aerial applications of chemicals to the corn fields across the street from my home, which sometimes took place while my children were playing outdoors when they were young. Since then, I have been concerned about exposure resulting from drift and its long-term effect on my children and me.

11. I am aware that in 2007 NRDC and the Pesticide Action Network of North America petitioned EPA to revoke all tolerances and cancel all registrations for chlorpyrifos.

12. I am worried about this administration's attack on our environment and environmental safeguards, such as the decision not to ban chlorpyrifos. I literally do not sleep well. I worry about waking up to find out what the administration has done to destroy our environment and environmental safeguards.

13. EPA has proposed to ban chlorpyrifos and has never reversed its findings that support the proposed ban. If EPA banned chlorpyrifos, I think that would reduce my concerns about unwanted exposure to this dangerous pesticide. The longer EPA takes to act on chlorpyrifos, the longer my family and I risk being exposed to this dangerous chemical.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct, to the best of my knowledge, information, and belief.

Executed this 19 day of January, 2018, at 5:15 p.m.

Sharon Bolton

SHARON BOLTON

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,Respondents.

Declaration of Sylvia Youngblood

I, SYLVIA YOUNGBLOOD, declare and state as follows:

1. I have been a member of the Learning Disabilities Association of America ("LDAA") for about six years, and I have been advocating for people with learning disabilities for over 25 years.

2. I live in El Monte, California, and I am very active in my community, particularly in working with other parents who have children with learning disabilities. I am the mother of four children, now ages 16 to 28, who all have specific learning disabilities. I am part of our local community advisory on special education, and I worked with our Soroptimist chapter to develop a scholarship fund for students with disabilities.

3. As a member of LDAA, I participate on a number of committees. I am the chair of our justice committee, where we talk about how learning disabilities funnel children into the school-to-prison pipeline. I am also on our public policy committee, finance committee and our development committee, and I serve on our Healthy Children Project. LDAA created the Healthy Children Project to raise awareness, promote policies and practices, and to build a nationwide network of LDAA members to protect children's health and reduce toxic exposures. Our mission is to: 1) Raise awareness of environmental factors, particularly toxic chemicals, that can harm brain development, contributing to learning disabilities and behavior disorders; 2) Promote policies and practices to prevent toxic chemical exposures, especially among pregnant women and children; and 3) Build a nationwide network of LDA members working to protect children's health and reduce toxic exposures that may lead to learning disabilities in current and future generations. I also advocate on behalf of individuals with learning disabilities and educate community members from a parent and advocate standpoint. I help parents navigate the school system, which is especially hard for parents of children with disabilities.

4. Raising children with learning disabilities is a challenge to say the least. Once you accept that this is your "normal," it gets a little easier, but it is always a fight and always a battle. I don't have the experience of just packing a lunch, sending my kids off to school, and talking about our days at dinner. I would go to work and get calls from the school telling me I need to pick up my kids, that they are being suspended, that they got "F" report cards. Some days at work I just look at the phone and hope that it won't ring. Being at my children's school is part of my day-to-day life, and I've had to get to know the school, the teachers, and the administrators very well. It can be really stressful and I have had to work to develop my advocacy skills. Sometimes I would just burst into tears wondering why the school hated my

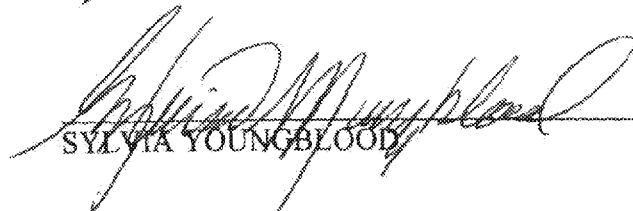
child. I have had school staff tell me directly that they don't want my kid there. As a parent, you take that personally because that is your child. It is very emotional.

5. Chemicals like chlorpyrifos that can cause learning disabilities should not be allowed to be used on our food. It is cruel to inflict those harms on families. At my son's high school, they have a salad bar, which is wonderful, but I worry about what chemicals are on that produce. I do not know that he is always, or ever, receiving organic foods. I appreciate that we are pushing fruits and vegetables on our kids while they're at school, but I want to know that they are actually healthy and that my son is not being exposed to harmful pesticides.

6. If EPA knows that chlorpyrifos has the potential to create these effects in pregnant women and children, and I understand that EPA has made such findings, then shame on them for manufacturing kids with learning disabilities. They do not understand the real effects and costs that their action (or lack of action) creates in terms of medical costs, educational costs, and prison costs, as well as emotional costs to families. I urge the Court to order EPA to take long overdue action and protect our children from chlorpyrifos.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 16 day of January, 2018, in El Monte, California.


SYLVIA YOUNGBLOOD

NO. 17-71636

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,

Petitioners,

STATE OF NEW YORK, *et al.*,

Petitioner-Intervenors,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, *et al.*,

Respondents.

Declaration of Virginia Ruiz

I, VIRGINIA RUIZ, declare and state as follows:

1. I am the Director of Occupational and Environmental Health at Farmworker Justice (“FJ”), a national advocacy and education organization whose mission is to support farmworkers in their efforts to improve their living and working conditions. My job responsibilities include educating the public, government officials and lawmakers about the adverse health impacts to farmworkers and their families from exposure to pesticides, and the need to reduce their exposure to such toxins. I work with farmworkers and community-based organizations across the U.S. to help workers and their families understand these occupational hazards and how to prevent pesticide-related illness and injuries. I also assist legal services programs and community organizations with developing outreach materials, accessing and

understanding pesticide and work safety laws and regulations.

2. I submit this declaration based on my personal knowledge and based on more than 20 years' experience as a farmworker advocate. I have been working in my current position for 17 years, advocating to protect workers from pesticide poisoning and other workplace hazards. Prior to working at FJ, I was Staff Attorney for California Rural Legal Assistance's Indigenous Project, representing indigenous migrants from southern Mexico and Guatemala. I have a law degree from Stanford Law School.

3. FJ has long advocated for more comprehensive protection of workers from exposure to pesticides, particularly the highly toxic organophosphates such as chlorpyrifos. The organization has submitted numerous and extensive comments during the registration review process for chlorpyrifos and other pesticides, and during the rulemaking process for worker protection regulations.

4. FJ helped prepare comments that were submitted to EPA on January 5, 2016, on behalf of a large coalition of farmworker unions, farmworker advocates, and environmental advocates. The comments supported EPA's proposed rule to revoke all food tolerances of chlorpyrifos. *See* 80 Fed. Reg. 69,080 (Nov. 6, 2015).

5. In November 2016, EPA published its Revised Human Health Risk Assessment of chlorpyrifos, which found, among other things, that there are no safe levels of the pesticide in food or water, that unsafe exposures to farmworkers continue on average 18 days after applications, and that workers who mix and apply chlorpyrifos are exposed to unsafe levels even when using protective gear and engineering controls.

6. Consistent with its mission, FJ was pleased with EPA's findings, and we were hopeful that farmworkers' exposure to chlorpyrifos would soon end. FJ submitted comments

to EPA on January 17, 2017, along with other farmworker and environmental advocates, urging EPA to revoke all food tolerances of chlorpyrifos.

7. We were outraged when EPA announced on March 29, 2017 that it would not ban any current uses of chlorpyrifos, despite the overwhelming evidence that the pesticide harms children, workers and the environment. FJ is very concerned that continued use of chlorpyrifos puts thousands of farmworkers and their families at risk for serious injury or illness every day.

8. EPA's failure to adequately assess and constrain the risks of chlorpyrifos results in adverse health impacts among workers and their families, and contamination of their communities. FJ will continue to provide technical assistance to farmworkers and farmworker advocates to help farmworker communities avoid exposure to chlorpyrifos and prevent adverse health effects. FJ will devote scarce resources to protect workers from chlorpyrifos, through legal support, research, and advocacy on their behalf. If fewer people were exposed to chlorpyrifos, FJ could devote more time and resources to other important issues impacting farmworkers, including other workplace hazards, substandard wages, discrimination in the workplace, and sexual harassment.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 19th day of January 2018, in Washington, DC.



Virginia Ruiz